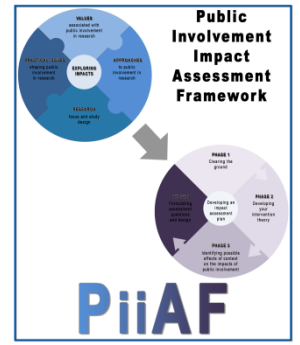
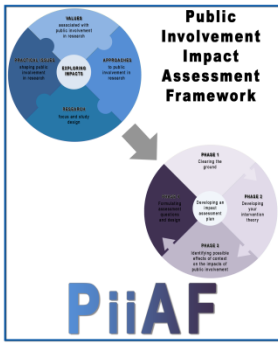




PiiAF

# The Public Involvement Impact Assessment Framework Guidance

Popay, J and Collins, M (editors) with the PiiAF Study Group

January 2014

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# Introduction

## Public involvement in research and its impacts

Over the past decade there has been increasing interest in involving members of the public in decisions about which research should be done, how it is done and how the results are disseminated. The term ‘members of the public’ is used here to refer to users of services (e.g. patients and carers) and members of groups who share a particular interest, for example, residents of particular neighbourhoods. Today the public are involved in many research fields, from health care to local history, and in many different ways.

Public involvement has been particularly rapid in health research in the UK where most major funders now require applicants to involve relevant members of the public in their research. There has been a growing interest in assessing the impact public involvement has on the people involved - both researchers and members of the public - and on the research. There is some evidence that these impacts are many and varied and both positive or negative. However, there is relatively little research in this field and much is of poor quality.

Some people argue that the public have a right to be involved in research and therefore the impact of this involvement does not need to be studied. However, in the research underpinning the PiiAF we explored the views of a wide range of people<sup>1</sup> and the majority agreed that the impacts of public involvement in research should be assessed arguing that:

- It's just good practice to assess interventions, of which PI is one
- There is a need to justify cost and other resources for PI
- Evidence on positive impacts may help to convince PI sceptics
- Funding for PI may be based on evidence that it makes a difference
- Assessment may help to improve the quality of PI
- There may be harm or limitations which we need to take steps to avoid
- Because members of the public want to know that they have made a difference

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<sup>1</sup> For more information please see the Delphi study final report: *Exploring areas of consensus and conflict underpinning values and impacts of public involvement in health and social care research: A modified Delphi technique.*

Most people also accept that assessing the impacts of public involvement is challenging. This is because of the different types of research, the diverse reasons researchers have for involving the public, the different types of people who are involved, the different ways they are involved, the different environments in which the research takes place and the diversity of possible impacts on the research process and the people and researchers involved.

The complexity of public involvement in research means that there can be no 'quick fix' - no single method - that can be applied to assess the impacts it has on the public who get involved, on the research team and on the research. People who want to assess these impacts have to carefully consider a range of issues to help them decide what impacts they want public involvement to have; whether they can reasonably expect their approach to public involvement to have these impacts; and then design an appropriate method to assess whether these impacts are achieved, as well as what, if any, unintended impacts there were.

### The Public Involvement Impact Assessment Framework

This document describes a **Public Involvement Impact Assessment Framework (PiiAF)** and provides guidance on its use. The PiiAF is based on research undertaken by the authors with funding from the Medical Research Council's Methodology Research Programme. A brief overview of this research is provided in Annex 2. We have also included a glossary in Annex 3 explaining how we are using some of the key words and phrases in this field.

The PiiAF and related guidance is primarily aimed at researchers who wish to design an assessment of the impact of public involvement in their research. However, we strongly encourage research teams using the PiiAF to involve relevant members of the public in the development of their plans to assess the impact of public involvement and we also hope that members of the public who get involved in research will find the PiiAF useful. The guidance is intended to be used when research ideas and funding proposals are being developed, to prompt discussion and consideration of how the impacts of public involvement can be assessed. However, it may also be used in the context of ongoing research projects. Funding bodies may also use it to encourage applicants to reflect on the impact of public involvement. Although the primary aim of the PiiAF is to help people plan how to assess the impacts of PI it may also help people think about how they can best

involve the public in their research. Some of the people who have reviewed the PiiAF and this guidance have also found it to be a valuable training resource.

In resources linked to the guidance we have included information about study designs and specific methods that researchers have used in the past to assess the impacts of public involvement. However, PiiAF is not an assessment tool kit but a framework for building an impact assessment plan. We have included very few references to other work in the body of the text, restricting these to direct quotes. However, we have compiled a list of further reading to give an indication of the literatures we have drawn on and to point users of the guidance to more detailed discussions of the issues raised (Please see Annex 4).

## The structure of the guidance

As Figure 1 illustrates, there are two parts to the guidance. Part 1 focuses on the **Public Involvement Impact Assessment Framework -PiiAF-** and Part 2 on designing an impact assessment plan.

Part 1 begins with an overview of the five elements in **PiiAF**:

- The values associated with public involvement
- Approaches to involving the public in research
- Research focus and study design
- Practical issues that can impinge on the process of public involvement and/or the impacts it can have
- The impacts of public involvement

Each of these five elements and related issues are then presented in more detail and one or two questions are posed to encourage users of the guidance to explore the implications for their own impact assessment plans. We have also provided a record card so that users can record key points from their discussions to use as they design their assessment plans.

The five elements of the **PiiAF** are presented in the order we feel is most logical. Users of the guidance may choose to address the elements in a different order, not engage with all of them or to consider them in more or less detail. Users will make these decisions on the

basis of their own needs and experiences and the constraints they are operating under, including the time they have available. However, we believe that the values people hold about public involvement can be a powerful influence on the process of involvement and the impacts it can have. Values are therefore central to the PiiAF and we recommend that everyone wishing to assess the impact of PI in research spend some time considering the issues associated with values.

The second part of the guidance is designed to support researchers to develop a plan to assess the impact of public involvement in their research. It takes people through four phases:

- Laying the Foundations - answering some preliminary questions
- Developing an intervention theory: a description of how you think your approach to involving the public in your research will lead to the impacts you want
- Identifying how aspects of the context in which your research will take place might affect public involvement processes and the impacts it can have.
- Designing your impact assessment – identifying what data to collect and how

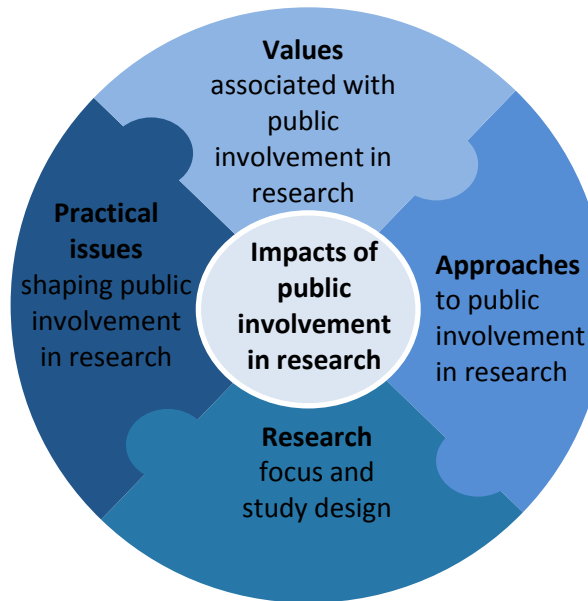
Finally, we have provided a series of resources to help users to explore issues raised in Part 1 and support them in developing their impact assessment plan in Part 2. These include:

- Summaries of information about the five PiiAF elements based on our own research and that of others.
- Resources to stimulate discussion about issues associated with the PiiAF elements. See PiiAF website – <http://www.piiaf.org.uk/>
- In-depth information relevant to each element, including key references
- Searchable databases of previous research evaluating the impact of PI in research and the tools and techniques that have been used.

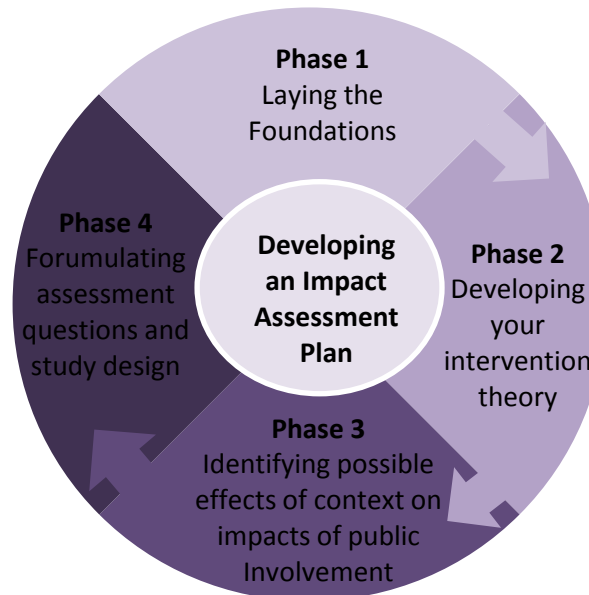
Figure 1: The Structure of the PiiAF Guidance

## Part 1: Using the PiiAF to explore impacts and how they are shaped

| Recording key points from your discussion |  |
|-------------------------------------------|--|
| Values                                    |  |
| Approaches to PI                          |  |
| Research Focus and Study Design           |  |
| Practical Issues                          |  |
| Identifying the Impacts of PI in Research |  |



## Part 2: Developing an impact assessment plan



We present each of the 5 elements in turn in this Guidance. For each element we include sections on:

- Key issues for that topic
- Questions for discussion and debate
- A resource list

A series of resources are provided to support users of the guidance including:  
 Summaries of more information on a topic  
 Resources to stimulate discussion of issues raised in PiiAF  
 In-depth information and reference lists  
 Searchable databases of previous impact studies and tools and techniques to assess impact

A **recording card** is provided to capture points arising from discussion of each element in Part 1. This record card provides the building blocks for developing an impact assessment plan in Part 2

## Part 1: The Public Involvement Impact Assessment Framework

The Public Involvement Impact Assessment Framework is intended to facilitate robust approaches to the assessment of the impacts of PI - but these assessments are far from straightforward. Public involvement in research is a complex social process comprising *“a number of separate elements which seem essential to the proper functioning... although the ‘active ingredient’ ..... that is effective is difficult to specify.”*<sup>2</sup>

This complexity means that it is unlikely that public involvement carried out in the same way would achieve the same impacts across different research projects. This makes it difficult to generalise from the methods used in one impact assessment to another. It is equally difficult to generalise about the findings of different studies of the impact of PI in research. The diversity in terms of the public who are involved and the aims of, and context for, involvement make it hard to predict where involvement would have the greatest impact. The complexity of the interactions between the ‘active ingredients’ in public involvement makes it very difficult to attribute specific impacts to the involvement process in general or to different types of involvement. These factors also make it difficult to identify empirical evidence about how the elements shaping public involvement and its impacts are linked.

The main elements that influence public involvement in research and the impact this involvement can have are identified in the Public Involvement Impact Assessment Framework (Figure 2). Most obviously the impacts of public involvement will be shaped by the **approach** that you adopt i.e. the ways in which members of the public are involved in your study. For example, having public members of a study advisory group can be expected to have different impacts than involving members of the public in data collection and analysis. The approach to PI will be shaped in turn by the **values associated with public involvement** by members of your research team. The processes and impacts of public involvement will also be influenced by the **focus of your research**, the **study design** and by a wide range of **practical issues** including the human and material resources available.

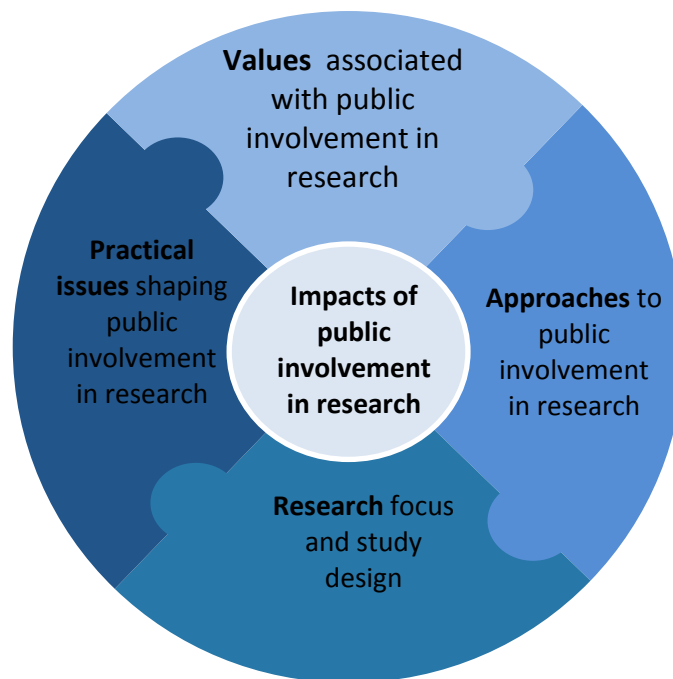
Understanding how each element of the PiiAF shapes involvement processes and impacts is essential to the design of an impact assessment, ensuring that it is able to take account of

---

<sup>2</sup> MRC Health Services and Public Health Research Board (2000). *A framework for development and evaluation of RCTs for complex interventions to improve health: p.1*

the complexity described above. For example, identifying the practical issues which might affect the process of involvement will help you report key features of the context in which public involvement took place and help you consider how the context affected the impacts you identify.

**Figure 2: The elements that can shape the impact of public involvement in research**



In the next sections we discuss each element of the PiiAF in the following order:

- Values about public involvement
- Approaches to public involvement
- Research focus and study design
- Practical issues associated with research
- Impacts of public involvement

For each element we:

- Provide a brief description
- Identify key issues associated with this element
- Pose some questions to help you explore the implications of these issues for your approach to PI and the types of impacts you can reasonably anticipate
- Point to resources that may help you think about the element

### *Record Card*

As you work through the following sections you are invited to consider the implications of the PiiAF elements for the impact of public involvement in your research. You may find it helpful to record your discussions on the record card provided. This information will provide useful building blocks in Part 2 as you develop your impact assessment plan.

| Recording key points from your discussion |  |
|-------------------------------------------|--|
| Values                                    |  |
| Approaches to PI                          |  |
| Research Topic and Study Design           |  |
| Practical Issues                          |  |
| Identifying the Impacts of PI in Research |  |



## ELEMENT 1

### VALUES ASSOCIATED WITH PUBLIC INVOLVEMENT IN RESEARCH

#### What do we mean by values?

A number of different ways of defining values are used in research and everyday conversations

Values associated with public involvement might relate to inter-personal issues (e.g. relationships between researchers and the public based on respect and trust), organisational (e.g. public involvement leading to research of greater quality and relevance to the healthcare system) or societal (e.g. accountability and transparency of research processes to the wider community)

Using our definition of values (see Annex 3: the glossary) we have identified three broad categories of values that are associated with public involvement:

- Ethical and/or political concerns associated with public involvement in research – we call these *normative values*
- Concern with the consequences of public involvement in research – we call these *substantive values*
- Issues associated with the conduct of public involvement in research – we call these *process values*

***What are the issues?***

Public involvement in research can challenge many of the values and assumptions that academic researchers hold. These may be values about what constitutes research quality or about the appropriate role of lay people in the research process.

The scientific values underpinning research may have positive and/or negative impacts on the processes of public involvement and the people who are involved. For example, academic values may conflict with the needs and aspirations of members of the public involved in research. This may lead to negative experiences of PI and reduce its beneficial impact. Tensions between different values might disrupt relationships during the research process and affect the impacts of PI and the outcomes of the research itself.

It is very likely that research teams including members of the public involved in your research, will hold different values about public involvement in research. It is important to acknowledge these values as they will shape the impacts that people anticipate from the public involvement. It is also important to acknowledge values as early as possible in the research process - ideally when the research is being designed so that strategies for managing potentially conflicting values both within the project team and the wider organisational or funding context can be developed. Values associated with PI operating in the inter-personal, organisational and societal domains may impact differently and/or cumulatively on the PI process and the impacts PI may have.

### **Questions for discussion**

What values about PI are held by you and other members of your research team?

What values about PI can you identify in the organisation(s) in which your research will be based?

How might these values shape your approach to public involvement, the involvement processes and the impacts public involvement can have?

Do you think there is any potential for conflict over the values associated with public involvement in your team and/or the organisation(s) in which the research will be based?

What processes can you put in place to manage divergent values?

- Within your team
- In the organisation(s) where public involvement will take place
- In the organisation funding your research or from which you intend to apply for funding

How might an impact assessment be designed to take into account the values you have identified in your team and the potential for conflict between values?

| Resource number | Description                                                                                                                                                                                                                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Resource #1     | Summary of findings from a review on values and PI in research                                                                                                                                                                                                                                                     |
| Resource #2     | Cards on the Table Discussion Resource: A game based on findings from our evidence review that aims to promote discussion of values associated with public involvement in health and social care research                                                                                                          |
| Resource #10    | Final report of research drawn from PiiAF study Group's Delphi research. <i>Exploring areas of consensus and conflict around values underpinning public involvement in health and social care research: A modified Delphi study.</i>                                                                               |
| Resource #11    | Published Paper: Grading, F, Britten, N, Wyatt, K, Froggatt, K, Gibson, A, Jacoby, A, Lobban, F, Mayes, D, Snape, D, Rawcliffe, T and Popay, J. 'Values associated with public involvement in health and social care research: a narrative review.' <i>Health Expectations</i> 2013 Dec 10. doi: 10.1111/hex.12158 |

**Record Card:**

| Recording key points from your discussion |  |
|-------------------------------------------|--|
| Values                                    |  |
| Approaches to PI                          |  |
| Research Topic and Study Design           |  |
| Practical Issues                          |  |
| Identifying the Impacts of PI in Research |  |

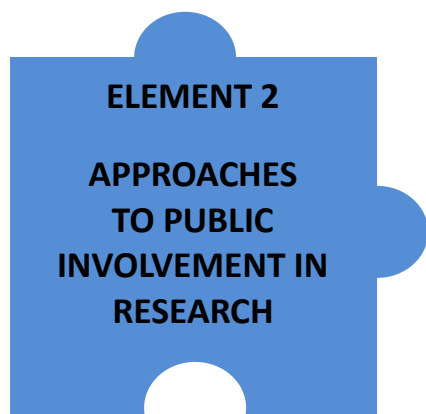
We have provided a series of examples of how the record card could be used to capture your project team's discussions about each element of the PiiAF. Examples 1 and 2 below illustrate how key points in discussions about values might be recorded in relation to two different types of research: a participatory qualitative research project to explore young peoples' decisions about smoking and a clinical trial evaluating an on-line relapse prevention package for people with bi-polar disorder.

***Record Card Example 1: recording values in research using participatory methodology***

|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Values</b> | A range of reasons for getting involved were identified. The majority relate to normative values associated with empowerment of young people along with aspirations to bring about real change and improvements to existing approaches to reduce smoking in young people disengaged from mainstream education. A couple of the academic researchers acknowledged the importance of public involvement in enhancing the quality and relevance of the research (substantive values). No apparent tensions between members of the project team and their values. The normative and substantive values held by the team also appear to be compatible. |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

***Record Card Example 2: recording values in clinical trial research***

|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Values</b> | General consensus that PI really crucial - but reasons varied and very helpful to make these explicit. Academic researchers with previous trial experience focussed a lot on PI as way to improve recruitment and retention rates as this is biggest challenge in trial. Clinicians believed service users have right to take part and will improve research experience for participants if input to measures, recruitment strategies, data collection process etc. Service users keen to ensure people find out about how to take part and that findings are disseminated as widely as possible. Want to avoid this being just an academic exercise! |
|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



### **What do we mean by approaches to public involvement?**

There are many different ways of categorising approaches to involvement. Some categorisations are presented as hierarchies, with one approach being seen as inherently better than another, but not everyone agrees that this is appropriate.

Distinguishing between the general approach to involvement (e.g. consultation, collaboration, control), the specific methods (e.g. service user researcher, public members of a project advisory group or a consultative panel) and the activities undertaken (e.g. commenting upon a research proposal, peer interviewing) can contribute to a more sophisticated understanding of how the involvement might have an impact.

**What are the issues?**

The approach to PI, the specific methods used and the activities the public get involved in (as well as the interaction between these dimensions) will shape the impacts PI has on research processes and outcomes. Revealing these complex pathways can be difficult.

If the PI processes are problematic then the beneficial impacts may be reduced.

Different research projects may require different approaches to public involvement as well as different kinds of lay expertise.

PI needs to be designed to suit the particular research study and may involve more than one approach and/or different PI approaches, methods and/or activities at different stages in the research.

The evidence base on PI will be improved if researchers are clear and transparent about their approach to PI, the impacts they wish PI to have and the pathways linking these two.

**Questions for discussion**

What do you consider your overarching approach to PI to be and what specific methods will you adopt?

Which aspects of your public involvement approach and methods might potentially act as barriers and/or facilitators to achieving the impacts you hope for?

How might you address these barriers?

| Resources       |                                                                                                                                                                                               |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Resource number | Description                                                                                                                                                                                   |
| Resource #3     | Tokenism: interactive resource to prompt discussion about how tokenistic approaches to public involvement might be avoided based on the findings from the PiiAF study group's Delphi research |
| Resource #12    | Draft standards for public involvement drawn from the PiiAF study group's evidence review                                                                                                     |

**Record Card:**

| Recording key points from your discussion |  |
|-------------------------------------------|--|
| Values                                    |  |
| Approaches to PI                          |  |
| Research Focus and Study Design           |  |
| Practical Issues                          |  |
| Identifying the Impacts of PI in Research |  |

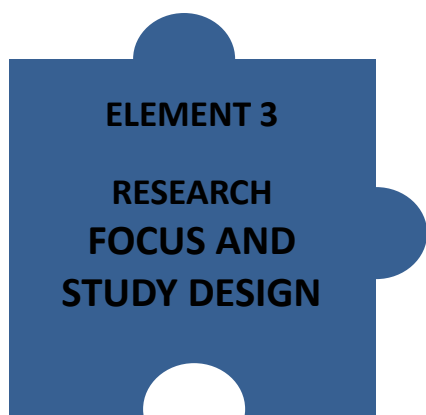
Examples 3 and 4 on the next page illustrate how the record card could be used to capture your project team's discussions about approaches to public involvement in research using the same two projects: a participatory qualitative research project to explore young people decisions about smoking and a clinical trial evaluating an on-line relapse prevention package for people with bi-polar disorder

***Example 3: Using the record card to record key points from discussions about approaches to public involvement using participatory methodology***

|                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Approaches to PI | <p>The project is participatory. The young people taking part as participants are also involved in key decisions regarding the design of the project. Feel very lucky to have found a small amount of funding to get the young people involved in designing the project and developing the funding proposal. APPROACH TO ASSESSMENT OF PUBLIC INVOLVEMENT IMPACT ALSO NEEDS TO BE PARTICIPATORY. Currently using workshops where young people are collaborating with academic researchers on the design of the project and proposal writing. Will set up a more formal Advisory Group with a smaller number of young people to oversee the project. The main barriers are the amount of time it will take involving the young people in this way – so need to make sure that timelines are clear. Also, unsure what will happen if disagreements between the young people and the academic researchers about the direction of the project occur – need to set up ground rules.</p> |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

***Example 4: Using the record card to record key points from discussions about approaches to public involvement in a clinical trial***

|                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Approaches to PI | <p>The idea for the trial (evaluating an online relapse prevention package for people with bipolar disorder) came out of discussion within research team which includes 1 service user. Have set up a focus group to develop ideas around design and application for funding. If funded – these will be invited to form a service user reference group who will be represented at all levels including project management group, and Trial steering committee. Ensure user involvement throughout. Also considering employing service users to carry out qualitative interviews about experiences of intervention. Currently looking at feasibility of this</p> |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



***What do we mean by Research Focus and Study Design?***

The **research focus** includes the discipline or field within which you are working (e.g. health services research, public health, mental health, etc); the population the research is concerned with (e.g. people with experience of a particular health problem) and the specific research question the research is addressing (e.g. effectiveness of a new treatment for diabetes or users' experience of a particular service and/or their health needs).

The **study design** refers to the type of methods used in the research at a macro level (e.g. randomized controlled trial; qualitative ethnography) and at a micro level of data collection (e.g. face to face interviews, clinical tests).

Describing your study design when you are reporting on public involvement will help to improve the evidence base on PI impacts.

***What are the issues?***

Decisions about which approach to adopt to PI and the processes of PI within a research project will be affected by the type of research you are doing.

Public involvement and its impacts in qualitative research may be different from that in clinical studies.

Different populations may have different experiences of being involved in research, different reasons for getting involved and different expectations of involvement. This may affect their willingness, or the extent to which they wish, to be involved.

There may be particular ethical or practical issues with involving particular groups e.g. children or people with dementia. This does not mean these groups should not be involved but careful consideration needs to be given to how best to do this.

Public involvement may have different impacts at different stages of your research project – it is important to take this into account when designing your impact assessment.

### Questions for discussion

What is your research topic and what will your study design be?

What are the main implications of your research topic and study design for the general approach(es) to public involvement you plan to adopt and the specific method(s) you will use?

At what point in your research process do you anticipate public involvement will have an impact?

How will you address any potential barriers to public involvement that result from your research topic and design?

How will your research topic and design shape the type of PI impacts you might expect to see?

### Resources

| Resource number | Description                                                                                                                                              |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Resource #4     | Research Topic and Study Design database: Signposting resource showing existing studies that have assessed PI impact within a range of research contexts |

**Record Card:**

| Recording key points from your discussion |  |
|-------------------------------------------|--|
| Values                                    |  |
| Approaches to PI                          |  |
| Research Focus and Study Design           |  |
| Practical Issues                          |  |
| Identifying the Impacts of PI in Research |  |

The use of the record card to record key points from discussions about the implications of particular research foci and study designs for public involvement and its impacts is illustrated below in examples 5 and 6 using the same two study examples.

***Example 5: Using the record card to record key points from discussions about research focus and study designs using participatory methodology***

|                                 |                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Research Focus and Study Design | The research focus is an exploration of how young people disengaged from mainstream education smoke, resist smoking or don't smoke. Intend to give young people some control over how the research is conducted – there's a sense that previous research has been 'done to' rather than 'done with' them. The study design is qualitative participatory action research. |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

***Example 6: Using the record card to record key points from discussions about research focus and study design in a clinical trial***

|                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Research Focus and Study Design | RCT to evaluate online relapse prevention package for people with Bipolar Disorder, compared to a wait list control. Follow-up over 12 months. Recruitment and retention are likely to be key challenges. Aim is to have user involvement at all levels including project management team. Aim is to input to protocols for all stages of trial including building relationships with participating NHS Trusts, communicating with service users so they know about trial, recruitment process, assessment process, consent training, data storage, analysis, interpretation and dissemination of findings. Challenges are around identifying wider pool of people for focus group, maintaining input throughout the project in way that is most feasible (could use regular skype / email as well as face to face meetings) and how to fund activity during grant development. Also need to consider training and support for service users involved, and how to maintain process if service user lead is off sick (which has been a challenge previously). |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



## ELEMENT 4

### PRACTICAL ISSUES THAT CAN INFLUENCE PUBLIC INVOLVEMENT AND ITS IMPACTS

#### ***What do we mean by Practical Issues?***

There are many practical issues that could impinge on the approach to PI you choose to adopt and on the processes of PI once your research has begun. These can arise within the organisations in which researchers are based or from other sources, including the organisation funding the research.

Our evidence review and Delphi study identified a range of practical issues relevant to PI including: the availability of training, the level and type of resources to support public involvement, issues associated with the payment of fees and expenses, access to information and travel and accommodation.

***What are the issues?***

Practical issues that may shape public involvement processes can be found at the personal (e.g. physical mobility), organisational (e.g. policies for public involvement such as paying people) and societal (e.g. accessibility of funding mechanisms for public involvement) levels.

Practical issues may make it more difficult for some groups to get involved for example people with disabilities.

Practical issues associated with public involvement such as funding and time may affect public involvement processes, reducing the beneficial impacts on the research and the people who get involved.

Practical issues might also interact to produce a cumulative impact on public involvement. For example, insufficient funding for public involvement may increase inequality in access to involvement for some groups.

Practical issues associated with public involvement need to be reported in sufficient detail in an impact assessment process to allow judgements to be made about whether they acted as barriers or facilitators.

The context in which public involvement is happening may change throughout the course of a research project (e.g. the members of the project team may change affecting the level of involvement expertise, resources may be reduced or changes to the tax and benefit systems may create problems with paying people for their involvement).

### Questions for discussion

What are the most important practical issues that might influence your public involvement and what consequences could they have for the impacts you wish involvement to have?

How will you address the potential barriers to your public involvement that might be caused by practical issues?

How might you design an impact assessment to take into account the practical issues you have identified including the different levels of practical issues (e.g. personal, organisation and societal) that could influence PI and potential changes in the context for your research?

### Resources

| Resource Number     | Description                                                                                                                                                  |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Resource # 6</b> | Practical Issues board game: interactive resource to prompt discussion about how practical issues associated with public involvement might influence impacts |

**Record Card:**

| <b>Recording key points from your discussion</b> |  |
|--------------------------------------------------|--|
| <b>Values</b>                                    |  |
| <b>Approaches to PI</b>                          |  |
| <b>Research Topic and Study Design</b>           |  |
| <b>Practical Issues</b>                          |  |
| <b>Identifying the Impacts of PI in Research</b> |  |

The use of the record card to record key points from discussions about the implications for public involvement and its impacts of a range of practical issues is illustrated below in examples 7 and 8 using the same two study examples.

***Example 7: Using the record card to record key points from discussions about practical issues using participatory methodology***

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Practical Issues</b> | <p>So far young people are enthusiastic so need to think carefully about how to maintain this – make research time-limited, focused, provide relevant rewards, good feedback about difference they are making.</p> <ul style="list-style-type: none"> <li>• Geographical distance might affect number and expense of meetings,</li> <li>• Training for young people and academic researchers will be very important – need to identify training needs, where such training can be obtained and make sure enough money to cover it in the budget</li> <li>• Need to think about and ask young people about their support needs and the mechanisms by which this can be provided</li> <li>• Time – participatory approach likely to take longer than conventional research – but project must proceed at a good pace to maintain young peoples’ interest and also because the young people might move on from the unit and therefore be unavailable</li> <li>• Organisation – Recent changes to the way members of the public get paid for involvement in our institution – need to ensure we are on top of the new process and monitoring how well/whether it is working</li> </ul> |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

***Example 8: Recording key points from discussions about practical issues in clinical trials.***

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Practical Issues</b> | <p>Everyone keen in theory, including funders, and host institution but infrastructure often not there</p> <ul style="list-style-type: none"> <li>-How to get funding for PI BEFORE funding awarded?</li> <li>-How to identify people with relevant skills and broad range of experience – selection process?</li> <li>-Communication: effective but not too costly? Skype / email?</li> <li>-Training and support – do we have capacity – be realistic! Need sufficient pool of people to make sustainable if people become unwell during process and are unable to participate</li> <li>-Honorary contracts, research passports, CRB checks etc all need to be considered –difficult for people with unclear work history etc. Documents required are often not available</li> <li>-Need to be able to cover costs up front. Can’t expect people to pay expensive travel etc and claim back</li> <li>-How to resolve conflict? Eg service user may not like randomisation rather than choice – but methodology demands it</li> </ul> |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## **ELEMENT 5**

### **IMPACTS OF PUBLIC INVOLVEMENT IN RESEARCH**

#### ***What do we mean by identifying the Impacts of PI in Research?***

Our evidence review identified a wide range of impacts associated with PI in research.

Impacts can be classified as relating to the research (e.g. research instruments, outcome measures, data collection, design and delivery, time and cost) or to the people involved (e.g. members of the public involved in research, academic researchers and funders).

Some impacts may be seen in the short term (e.g. on patient information documents) others may take longer to be seen or be more complex to identify (e.g. on recruitment and/or retention) or on the individuals who got involved?

Public involvement can have an impact on all stages of the research process from topic prioritisation through to dissemination.

Impacts of public involvement can be experienced as positive or negative. They may also be intended or unintended.

***What are the issues?***

Identifying the impacts expected at the beginning may shape the processes and actual impacts of public involvement.

It is important to be mindful of the potential for public involvement to have unanticipated impacts and to look for negative impacts as well positive impacts.

The experience of an impact as positive or negative may vary within a research team.

Some pathways between public involvement and particular impacts are more difficult to establish than others e.g. choice of topics or outcome measures by members of the public may be easier to identify when involvement was through consultation than when it involves a collaborative process.

Much reporting of the impacts of public involvement is of a low quality. In particular, it is important that both positive and negative impacts should be reported.

The introduction of the Research Excellence Framework (REF) to assess research quality in UK higher education institutions has brought an increased focus upon the impact of research beyond academia. Public involvement and the assessment of its impact could make a major contribution to demonstrating this wider impact.

Expectations about the kinds of impacts public involvement may have on a study should form part of a dialogue between research project team members and the public involved.

### Questions for discussion

Which impacts for public involvement do you wish to prioritise in your research?

Are there any potential negative impacts and how will you identify these?

How will you acknowledge and address the different impacts that might be expected by the different project stakeholders (including members of your project team, advisory groups, funders)?

How can divergent views (if there are any) within your project team about the impact of public involvement be resolved?

How might an impact assessment be designed to take into account any unintended impacts of your public involvement that may occur?

### Resources

| Resource number | Description                                                                                                                                                                                                                                     |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Resource #7     | Tabular summary of findings from a review of reported impacts of public involvement in research from PiiAF study Group's evidence review                                                                                                        |
| Resource #8     | What do you know impacts?: Interactive resource to prompt discussion about positive and negative impacts of public involvement on research and on people                                                                                        |
| Resource #9     | Database – Methods and tools to assess impacts Signposting resource to published case examples of methods and tools                                                                                                                             |
| Resource #10    | <i>Exploring areas of consensus and conflict underpinning values and impacts of public involvement in health and social care research: A modified Delphi technique.</i> Final report of research drawn from PiiAF study Group's Delphi research |

**Record Card:**

| Recording key points from your discussion |  |
|-------------------------------------------|--|
| Values                                    |  |
| Approaches to PI                          |  |
| Research Topic and Study Design           |  |
| Practical Issues                          |  |
| Identifying the Impacts of PI in Research |  |

The use of the record card to record key points from discussions about the impacts of public involvement is illustrated below in examples 9 and 10 using the same two study examples.

***Example 9: Using the record card to record key points from discussions about the impacts of public involvement using participatory methodology***

|                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Identifying the Impacts of PI in Research | <p>People: Public involved – Increased knowledge, skills, confidence and control; Researchers – increased knowledge, skills, effective research project; wider community – increased accountability of research to young people who smoke/don't smoke, enhanced relevance of research.</p> <p>Research: more appropriate/accessible research design and delivery; better quality/relevance of data collected; dissemination to have a greater impact; negative impact of time and cost</p> |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

***Example 10: Using the record card to record key points from discussions about the impacts of public involvement clinical trial research***

|                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Identifying the Impacts of PI in Research | <p>Could do this in very structured way eg stagger user involvement across sites and measure impact on recruitment rates, or participant experience. But the reality is that evaluating the impact of user involvement is not main focus of trial so too costly to do this way. Will do more qualitatively</p> <ul style="list-style-type: none"> <li>-compare our experiences with trials in which no user involvement</li> <li>-ask participants about experience of the research- how they found out about it, how felt about it, thoughts about being interviewed by users etc.</li> <li>-could have a go at drafting protocols for recruitment, retention, analysis, dissemination etc – and then take to service users and ask for additional input and see what specific changes this leads to – but may feel artificial and may prefer to do organically as a group. Depends on how much we decide evaluation is key</li> <li>-ask each member of research team to identify impact of user involvement on range of items using visual analogue scales – collate findings</li> </ul> |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

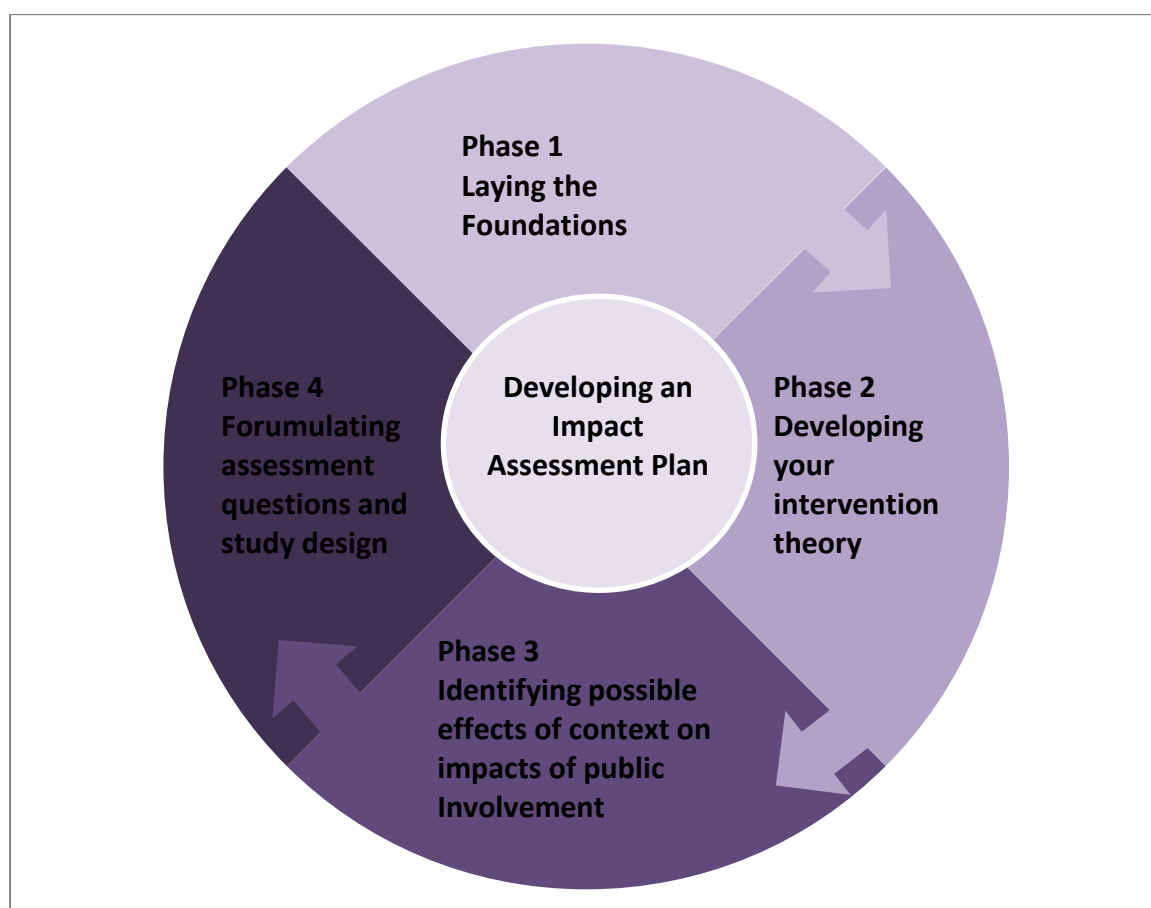
### **And finally.....**

You have come to the end of Part 1 of the guidance. In this part we described the main elements that we and others have identified as shaping the impacts of public involvement in research. You have been encouraged to discuss these issues with other members of your research team and with members of the public involved in your research in order to identify the aspects of these elements that may affect the impacts they can have. We hope that you found the issues and questions raised for each element relevant and the resources we provided helpful. If you used the record card to identify the key outcomes of these discussions you will find it useful to refer to this as you work through Part 2 of the guidance, which focuses upon designing an impact assessment plan.

## Part 2: Developing a plan to assess the impact of public involvement in research

This part of the guidance aims to help you to develop a plan to assess the impact of public involvement tailored for your research. In Part 1 the multiple elements that alone or in combination can affect these impacts were described. You were encouraged to identify the values held about public involvement by you and others in your research team and the impacts you would like public involvement to have. You were also asked to explore the ways in which your values, along with your approach to public involvement, your research focus and study design and practical considerations, could affect these impacts.

The ways in which particular aspects of these elements of the PiiAF may affect a particular impact are difficult to specify. This complexity leads to many challenges for those wanting to assess the impact of public involvement in research. To help you manage this complexity we recommend that you follow the four development phases in the diagram below. Each phase is considered in more detail in the following sections. If you completed the record card during Part 1 this will help you as you move through these phases.



# Phase 1

## Laying the Foundations

The key questions to consider here are:

- **Why do you want to assess the impact of public involvement in your research?**
- **Who should be involved in the design and conduct of the impact assessment?**

### ***Why are you carrying out an impact assessment?***

The reasons people have for wanting to assess the impact of public involvement in their research have implications for the way the assessment is undertaken. [Resource #9] Impact assessments have been divided into three types:

- Formative assessments would be concerned with improving public involvement processes. They involve cyclical feedback of findings to the research team so they can act to improve the involvement processes and/or activities as the research continues.
- Process assessments would be concerned to identify factors in the environment affecting the processes of public involvement - positively or negatively - and may also be formative.
- Summative assessments would be concerned to demonstrate the outcomes of public involvement in research, for example on activity recruitment levels. Typically, they involve relatively discrete data collection with findings being reported at the end of the assessment.

Often these types of assessment are used in combination.

### ***Who should be involved in the impact assessment?***

It is important to give early consideration to who should define the scope and purpose of the assessment and what is to be done with the findings. This may be a particularly sensitive issue if negative impacts of public involvement are found. Assessing the impact of public involvement can make relationships between the members of the public involved in your research and other members of the research team more complex. It is therefore important to involve everyone in discussions at an early stage. In particular you should consider:

- How members of the public will contribute to the impact assessment. There is some evidence that public involvement in the design and conduct of impact assessments has been limited even when public involvement in research has been extensive. Members of the public involved in your research should definitely be involved in the design of the impact assessment and may also contribute to other stages.
- Whether the impact assessment should be carried out by members of the project team or by people independent of it. It is important to think about possible issues of bias and potential conflicts of interest when considering who undertakes the assessment. Having an external assessor may give the findings more credence but this may not be feasible and will also have financial implications.

| <b>Resources</b>       |                                                                                                                            |
|------------------------|----------------------------------------------------------------------------------------------------------------------------|
| <b>Resource number</b> | <b>Description</b>                                                                                                         |
| <b>Resource #9</b>     | Database – Methods and tools to assess impacts:<br>Signposting resource to published case examples<br>of methods and tools |

## Phase 2

### Developing your intervention theory

The key question to consider here is:

- **How will your approach to public involvement lead to the impacts you want involvement to have?**

The next phase in designing an impact assessment is to produce an ‘intervention theory’- simply a description of *how* you think your approach to public involvement and the specific methods for involvement you intend to use will lead to the impacts you want. If you used the record card during Part 1 you will find it helpful to review your notes on how your values, approaches to public involvement, research focus and design and practical issues may impinge on impacts. Issues to consider include:

- The likelihood of multiple pathways between public involvement and particular impacts;
- The possibility that different members of the research team may have different ideas about these pathways. In particular, members of the public may have different ‘theories’ about how their involvement will achieve the desired impacts.
- Designing your impact assessment to test more than one ‘theory’.

Below we provide an example of how a research team might develop an intervention theory drawing on their record card. This example also highlights how the literature on public involvement might provide support for your ideas. We have included a bibliography (annex 4) to help you identify relevant literature. Reviews of research can be particularly helpful.

If you are unable to develop a logical explanation for why your approach to and methods for public involvement can be anticipated to have the impacts you want, you should consider whether you should and if you should whether you should involve people in different ways and/or revise your expectations of the impact you want from PI. [See further reading on complex interventions and assessment approaches in annex 4].

**Example: Developing a 'theory' of how Public Involvement will achieve desired impacts**

The team filling in the report card below placed a high substantive value on statistical generalizability in the context of a randomised controlled trial (study design). They plan to involve people with relevant experience in the design of recruitment leaflets (approach to public involvement) to help achieve the desired impact of a higher recruitment.

| Recording key points from your discussion        |                                                                                                                                                                                                                                  |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Values</b>                                    | High level of agreement amongst clinical colleagues (the majority on the research team) that main focus is upon ensuring rigour in our experimental approach and that a high level of statistical generalizability is necessary. |
| <b>Approaches to PI</b>                          | It's likely that our approach will be consultative using group discussion methods. We will draw on the skills and experiences of the existing user group attached to our centre in order to design a recruitment leaflet         |
| <b>Research Focus and Study Design</b>           | Randomised controlled trials. Design already been decided – developed quickly in response to NIHR call. Committed to high degree of PI in recruiting trial participants.                                                         |
| <b>Practical Issues</b>                          | Funding in place to remunerate public involvement and working with an existing user group. No need for ethics clearance for the public involvement, as they won't work directly with participants.                               |
| <b>Identifying the Impacts of PI in Research</b> | The main intended impact will be on an increased recruitment rate to the trial in comparison with previous trials we've conducted with no public involvement.                                                                    |

So this team needs to describe how public involvement in the design of a leaflet may increase recruitment. It may help them to look at the review by Staley (2009, pages 37-38) which sets out a number of different ways in which public involvement can affect levels of participation in research. This team might identify the possible explanations or hypotheses

set out in Table 1. The table also illustrates the kind of data they would need to collect to test these explanations. Their impact assessment could ‘test’ all of these theories or prioritise one or two of them.

**Table 1 Summary of impact assessment plans to test different intervention theories**

| Intervention theory                                                                                                                                                                                                 | Impact Assessment plan                                                                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Public involvement in writing recruitment leaflets could ensure that the leaflets were written in accessible language thus increasing the likelihood that potential participants agree to take part in the research | Record any changes in language resulting from public involvement                                                                                              |
| Public involvement in writing leaflets could result in more appropriate channels of distribution thus increasing recruitment by increasing the number of people being invited                                       | Record any changes in distribution channels suggested by members of the public                                                                                |
| Public involvement in writing leaflets could influence the content of the leaflets, thus increasing the likelihood that potential participants will be motivated to take part in the trial                          | Capture any changes in the way the research is explained as a result of public involvement and also record participants’ motivation for agreeing to take part |

| Resources       |                 |
|-----------------|-----------------|
| Resource number | Description     |
| Annex 4         | Further reading |

## Phase 3

Identifying how context  
may affect the impacts of  
PI

**The key question to consider here is how might the context in which your research will take place affect the process of public involvement and/or its impacts?**

The impacts of public involvement in your research will be affected by the context in which it takes place. Your assessment plans need to take these influences into account. The record card completed during Part 1 should help you identify key aspects of context relevant to your situation. These could include the following:

### ***The research itself, its focus and the study design***

- Are your desired impacts realistic in the context of your research? Some types of research may be more amenable to public involvement than others. For example, it may be easier for the public to contribute to the design and evaluation of lifestyle interventions than to methodological research. However, research suggests that public involvement can have benefits in a wide range of research contexts. [Resource #4].
- Are members of the public involved at appropriate points in the research process? The stage(s) at which members of the public are involved will shape the impacts. For example, to impact on the relevance of research (via the choice of outcome measures for example) or recruitment to trials (via patient information for example or the consent process) members of the public will need to be involved at an early stage of a study.

### ***Values and behaviours in the research team and in wider settings or organisations***

- How might the support, or lack of it, from key people, particularly senior members of your institution/funders, influence the impact of your public involvement activities? This can affect how your work is valued and hence the self-confidence of the public who are involved in it. It can constrain the opportunities for involvement or the speed with which expenses are reimbursed/fees paid. Constraints imposed by your organisation or funders may lead to tokenistic involvement and reduced impacts; conversely, well-supported involvement is more likely to have desired impacts.

***Practical issues including structures, procedures and resources***

- Do you have appropriate financial resources to support the public who are involved to deliver the desired impacts? Ideally resources should provide for out of pocket expenses and payment for preparing materials before a meeting, attending meetings and/or reviewing study documents. The availability of these resources demonstrates the value attached to public involvement, and can reassure members of the public that their contribution will be taken seriously.
- Are your financial and/or administrative systems fit for purpose? The contribution and therefore impact of public involvement is likely to increase when members of the public are given sufficient time to prepare for meetings and think about what they want to say in advance. A potential negative impact here would be overburdening members of the public by expecting too much preparatory work. Members of the public should be reimbursed in a timely fashion without undue bureaucracy and researchers should be sensitive to potential problems with the tax and benefit systems. Referring to existing guidelines or principles for best practice in public involvement may help to ensure that your public involvement has the impacts you are hoping for [Resource #9].

| Resources       |                                                                                                                                                          |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Resource number | Description                                                                                                                                              |
| Resource #4     | Research Topic and Study Design database: Signposting resource showing existing studies that have assessed PI impact within a range of research contexts |
| Resource #9     | Database – Methods and tools to assess impacts: Signposting resource to published case examples of methods and tools                                     |

## **Taking stock**

By this stage you should be clear about which methods for public involvement you will use and the impacts you wish public involvement in your research to have. Additionally, having worked through the first three phases in the development of your impact assessment plan your team, including public members, should have decided:

- Who should contribute to the development of your assessment plan and in particular what role the members of the public involved in your research will have;
- Whether you want to undertake a formative or summative assessment or a combination of both;
- Whether members of the research team will undertake the assessment or an independent person/team;

You should also have:

- Described how you think your approaches to involvement will lead to your desired impacts (*your intervention theory*) and
- Highlighted the most significant effects (either positive or negative) that the context in which your research will be conducted may have on these impacts.

This information will provide useful building blocks for the fourth and final phase in the development of an assessment plan, during which you will be supported to formulate your assessment questions and design the assessment. This will include deciding what data you want to collect, how you will collect it and what your approach to analysis will be.

## Phase 4

Formulating assessment questions and designing the assessment

The key questions to consider here are:

- What specific questions do you want your assessment to answer?
- What approach to impact assessment will you use?
- What specific data will you need to collect and how will you do this?
- What challenges will you need to address and which might limit what is feasible?

### *What specific questions do you want your impact assessment to answer?*

As in any research it is important to formulate clear and realistic questions, which your impact assessment will aim to answer. You may identify more than one question, particularly if different stakeholders (e.g. funders) and different members of the team have different perspectives on the desired impacts. The approach illustrated in Table 2 may help you formulate your questions. In this case the researchers wanted to assess whether:

- Involving young people (WHO)
- In advisory group discussions to help develop outcome measures (HOW)
- Produced evidence seen as more credible and relevant by young people (WHAT)?

*Table 2 Using the framework to generate your impact assessment question*

| WHO?                        | HOW?                                                                 | WHAT?                                                                                        |
|-----------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| Does involving young people | Via an advisory group helping to select appropriate outcome measures | Lead to evidence that is perceived to more credible and relevant by a range of stakeholders? |
|                             |                                                                      |                                                                                              |
|                             |                                                                      |                                                                                              |

You will find examples of research questions used in previous evaluations of the impacts of PI in our searchable database. [Resource #9]

### ***What challenges will you have to address***

There are significant challenges involved in assessing the impacts of public involvement in research. Some of these are highlighted below and you should consider whether these are relevant to you and, if they are, how you can address them in your impact assessment plan.

#### *The challenges created by 'noise' in the system:*

- The problem of attributing impacts to particular causes is not specific to public involvement. For example, changes in the illness status of people with a chronic illness do not necessarily predict changes in their quality of life [QOL] because other factors (e.g. practical help and financial security) help them adapt, so influence QOL outcomes.
- In the same way, it may not be possible to identify whether a successful change in recruitment strategy originated with a 'public' or academic member of a team/group. Sometimes, meeting minutes allow some attribution of responsibility, but often this is not the case. Research also suggests that more cohesive team dynamics make it more difficult to identify discrete impacts of PI. [See annex 4: Further reading]

#### *The challenges associated with assessing unintended impacts:*

- Assessments of impact, particularly those involving pre-specified quantitative measurement tools, may miss unintended impacts if there is no means built in to capture them. For example, impacts of the confidence of members of the public may be missed in assessments which focus only on impacts on recruitment. However, there are methods that can help here [Resource #9].

#### *The challenges of time to impact*

- Some impacts may take time to emerge and may not do so in the lifespan of your project. For example, patient involvement in an international collaboration developing common outcome measures for research on treatments for rheumatic conditions led to the development of a previously ignored outcome measure – tiredness - but it has taken more time for this to become widely used in research [See <http://www.omeract.org/>]

### *The challenges of ensuring the quality of your impact assessment*

- Whatever study design and data collection methods you use it is important to ensure that your assessments are of sufficient quality, if the evidence generated is to be convincing and of use to others. If you are not familiar with the literature it is worth looking at how quality can be assured in different research *paradigms* [See section on 'Further reading on complex interventions and assessment approaches' in annex 4].

### **What approach to assessing PI will you use?**

Once you have formulated research questions that are feasible to address you can decide on the most appropriate study design and methods to address them. A wide range of impacts of public involvement has been reported in the literature [Resource #7] and as our database of previous research illustrates, diverse study designs and methods have been used to assess these impacts - both quantitative and qualitative [Resource #9]. Your decision on study design and data collection methods should be driven by the purpose of your assessment and the questions you want to address. However, ideally you should aim to identify particular impacts, quantify them where appropriate and explore the processes leading to them. This will require a mixture of qualitative and quantitative methods and data.

The framework in Table 3 may help you move from your intervention theory and research questions to decisions on study design and data collection methods.

**Table 3 Framework for turning an objective into evidence** (Adapted from RCUK, 2011).

| <b>State your intervention theory</b><br>(Use Table 1)      | <b>Impact Assessment Question</b><br>(Use Table 2) | <b>Design</b>                                                                                                          | <b>Data collection methods</b>                                                                    | <b>Develop Measures/ Indicators</b>                             |
|-------------------------------------------------------------|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| <i>What is your public involvement intended to achieve?</i> | <i>Think about: Who, What and How</i>              | <i>Consider what study design is required to address these questions e.g. qualitative, quantitative, experimental,</i> | <i>Where will you collect the data from and how will you collect it e.g. interviews, diaries,</i> | <i>How will you assess whether an impact has been achieved?</i> |
|                                                             |                                                    |                                                                                                                        |                                                                                                   |                                                                 |

### ***How will you collect the data for your impact assessment?***

Depending on the approaches and methods for involvement you use, the type and range of impacts you are anticipating and the context in which involvement in your research is taking place, you may need to use more than one method to collect data. Some impacts may be best measured quantitatively, others qualitatively.

For example, you may be planning to involve service users in advising on a prototype service improvement to ensure it is acceptable to the target audience. Qualitative assessment of this impact could include identifying what improvements the public involvement made and then interviewing research participants about whether these improvements affected their experience of using the service.

The impacts on members of the public involved in your research could include increased confidence in their capabilities and a sense of being valued. These outcomes could be assessed using quantitative scales or counts of how often individuals contributed to discussions. Alternatively, you could explore qualitatively how they felt about their ability to contribute, the impacts this had on them and whether it was a positive or negative experience.

The type of data you collect will determine your approach to data analysis. In deciding on methods for data collection and analysis you may find it helpful to look at impact assessments that used study designs and methods similar to those you wish to use. [See resource #9] This resource also provides information on tools and techniques that have been used.

You will also need to decide when the assessment will be carried out. Ideally impact assessment should take place as soon as your research starts so you can establish baseline levels from which impacts can be assessed. Some impacts of public involvement (e.g. on team dynamics) will need to be assessed throughout the whole process of involvement, some (e.g. on recruitment) at the end of the research and some may not become evident until after the research has ended.

## Resources

| Resource number    | Description                                                                                                                              |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Resource #7</b> | Tabular summary of findings from a review of reported impacts of public involvement in research from PiiAF study Group's evidence review |
| <b>Resource #9</b> | Database – Methods and tools to assess impacts: Signposting resource to published case examples of methods and tools                     |

## **And finally.....**

You have reached the end of the PiiAF guidance. No doubt you still have work to do before you have completed your impact assessment plan. We hope you find the resources we have provided helpful in doing this.

One final thing to consider at an early stage in developing your impact assessment is whom you wish to disseminate your findings to and how. Possible audiences include:

- Members of the public involved in your research and researchers on your team
- The funders of your research and other research funders
- Other members of the public with experience of being involved in research
- The wider academic community, policy makers and the wider public

You need to think carefully about the way you present your results to different audiences. You may want to use different methods to give feedback to the public involved in your research than you would to inform the wider academic community. You also need to make sure that quality of your reporting is good. Common problems with reporting of public involvement<sup>3</sup> include a lack of detail on:

- The way public involvement has been defined in the study
- The way in which public involvement happened
- The methods used to assess the impact of public involvement (including any economic appraisal of impact if appropriate)
- The context in which the public involvement took place and how this may have affected the impacts being assessed.
- The impacts and outcomes being assessed.

In addition, it is also important to identify how your work links with and builds on the existing body of work on public involvement and assessments of its impact in order to ensure that the evidence base on the impact of public involvement in research is strengthened.

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<sup>3</sup> Staniszewska, S., Brett, J., Mockford, C., & Barber, R. (2011). The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. *International Journal Of Technology Assessment In Health Care*, 27(4), 391-399.

## Annex 1: Table of current (January 2014) resources linked to the PiiAF and guidance

These resources can be found on the PiiAF website: <http://piiaf.org.uk/>

| Resource Number | Description                                                                                                                                                                                                                                                                                                           |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| #1              | Summary of findings from a review on values and public involvement in research                                                                                                                                                                                                                                        |
| #2              | Cards on the Table discussion resource: a game based on findings from our evidence review that aims to promote discussion of values associated with public involvement in research                                                                                                                                    |
| #3              | Tokenism: interactive resource to prompt discussion about how tokenistic approaches to public involvement might be avoided based on the findings from the PiiAF study group's Delphi research                                                                                                                         |
| #4              | Research Topic and Study Design database: Signposting resource showing existing studies that have assessed PI impact within a range of research contexts                                                                                                                                                              |
| #6              | Practical Issues board game: interactive resource to prompt discussion about how practical issues associated with public involvement might influence impacts                                                                                                                                                          |
| #7              | Tabular summary of findings from a review of reported impacts of public involvement in research from PiiAF study Group's evidence review                                                                                                                                                                              |
| #8              | What do you know about impacts?: Interactive resource to prompt discussion about positive and negative impacts of public involvement on research and on people                                                                                                                                                        |
| #9              | Database – Methods and tools to assess impacts: Signposting resource to published case examples of methods and tools                                                                                                                                                                                                  |
| #10             | <i>Exploring areas of consensus and conflict underpinning values and impacts of public involvement in health and social care research: A modified Delphi technique.</i> Final report of research drawn from PiiAF study Group's Delphi research                                                                       |
| #11             | Published Paper: Grading, F, Britten, N, Wyatt, K, Froggatt, K, Gibson, A, Jacoby, A, Lobban, F, Mayes, D, Snape, D, Rawcliffe, T and Popay, J.<br>'Values associated with public involvement in health and social care research: a narrative review.' <i>Health Expectations</i> 2013 Dec 10. doi: 10.1111/hex.12158 |
| #12             | Draft standards for public involvement drawn from the PiiAF study group's evidence review                                                                                                                                                                                                                             |

## *Annex 2: Summary of research underpinning the PiiAF*

The Public Involvement Impact Assessment Framework was based on research undertaken by teams based at Lancaster University and the Universities of Exeter and Liverpool. It was funded by the Medical Research Council Methodology Research Programme and aimed to:

- Advance understanding of the impacts of public involvement in health and social care research
- Contribute to more robust assessment of these impacts and to improved standards of practice in PI in research.

The research addressed the following five questions:

- What is already known about the impacts of public involvement in research?
- How can these impacts be assessed and/or measured?
- What is known about the factors that are causally linked to these impacts?
- Can this evidence be used to develop 'good practice' standards for PI in research?
- What areas of consensus/conflict are there about values of PI in research?

The study design involved three elements:

1. Reviews of knowledge on Values, Impacts & Approaches to PI in research
2. A Delphi exercise to identify areas of consensus and conflicts around PI in research
3. Developing and piloting of the Public Involvement Impact Assessment Framework and associated guidance

The public were involved in the research in three main ways:

- The research team included three service user investigators with experience of facilitating public involvement in research
- Members of the public were recruited in NW and SW England to form a Public Advisory Group, which commented on all aspects of the research.
- A wider National Advisory Network also included members of the public/service users alongside academics and professionals with PI experience. The network met twice to advise on the strategic development and delivery of the project.

We also undertook an internal evaluation of the process and impact of public involvement in this research. This involved the periodic and systematic collection of views about and experiences of public involvement. Data were collected from all members of the research team and members of the Public Advisory Group. Findings from the internal evaluation were fed back regularly to the Public Advisory Group and to the project management team which sought to respond to any issues identified. The findings from the internal evaluation have also been used to develop resources for the PiiAF.

## *Annex 3: Glossary*

### **ACADEMIC RESEARCHERS**

We use the term academic researchers to include those people sometimes also referred to as 'researchers', 'clinical researchers' or 'professional researchers'. 'Academic researchers' refers to those people who would not primarily self-identify as public-involved, have undergone formal training in and have experience of conducting academic research.

### **APPROACHES TO PI**

This refers to the way in which PI within a project is organised. We have distinguished between approaches to PI which include consultation, collaboration and control and methods of PI which include service user researchers, public representatives on advisory groups, public-only project teams.

### **ASSESSMENT**

Assessment is finding out whether PI has made a difference. We use it to include all approaches to judging whether PI has had an impact including narrative reflections on PI impact and quantitative, standardised impact assessment tools.

### **ELEMENT**

We have called the components of the framework (e.g. Approaches to PI, Values) elements. For each element we discuss the issues and questions associated with it, provide some resources to support exploration of the element and signpost on to other sources of reading.

### **GUIDANCE**

The guidance is the resource we have produced to help people use the PiiAF. It is divided into two parts; the first part includes a detailed overview of the framework and its elements; the second part focuses upon how to design an impact assessment.

### **IMPACT**

We adopt a broad approach to understanding what 'impact' is. We take it to mean any difference that PI has made either to the research or the people involved in the research. We include short-term, medium-term and long-term impacts as well as outcomes. We recommend that project teams using the framework have a clear and consistent understanding of what they understand impact to be.

### **LAY EXPERTS**

Lay experts are people who would not primarily self-identify as academic researchers or health professionals who have lived experience of, for example illness or using a service. The expertise of lay experts is often contrasted with professional or academic knowledge.

### **METHODS OF PI**

The way in which PI happens within a research project such as employment of a service user researcher or public representatives on a Public Advisory Group is described as the Method of PI. We distinguish between Methods of PI and Approaches to PI (see definition above).

## **NORMATIVE DEBATES**

Normative debates are public discussions about rules or standards of behaviour that represent at least two different positions informed by values. An example of a normative debate would be where substantive research values such as objectivity or neutrality conflict with process-related values such as partnership or equality. The different value positions reflected in the debates are likely to inform what people expect or believe about, and/or do in PI in health and social care research.

## **PiiAF**

Our framework to help people think about the issues and questions associated with assessing the impact of PI in health and social care research. It consists of 5 elements: Values; Approaches to PI; Research Focus and Study Design; Practical Issues and Identifying the Impacts of PI in research.

## **PRACTICAL ISSUES**

We use practical issues to refer to all those material or tangible aspects of the context in which PI happens which might have an influence on its impact. For example the availability of training for PI might shape its impact.

## **PUBLIC**

Health researchers may refer to the people who participate in or who are involved in their research as “patients” but we use “public” to cover the wide range of people who may be recruited to research including carers, relatives of patients, ex-patients, staff of advocacy groups etc.

**INVOLVE** (NIHR) define public as: people who use health and social services; informal carers; parents or guardians; disabled people; recipients of health promotion/public health /social service interventions; groups exposed to potentially harmful substances or products (e.g. pesticides or asbestos); and organisations representing users of services<sup>4</sup>.

We feel that the general term ‘public’ may be more appropriate than ‘patient’ or ‘service users’ because people involved in research may not necessarily identify primarily as patients or they may be asked to draw upon experiences that go beyond their use of services.

## **PUBLIC INVOLVEMENT**

Throughout the PiiAF we draw upon INVOLVE’s definition of public involvement as “research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them”<sup>5</sup>. This refers to the involvement of members of the public in decisions about what the focus of research should be, how it should be carried out, analysed and disseminated.

The decision to use the term ‘public involvement in research’ rather than other terms is in part a pragmatic response to managing the diverse terminologies that have been used in the published papers which were reviewed. There would be practical difficulties with trying to ensure that all the

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<sup>4</sup> Hanley, B., Bradburn, J., Barnes, M. Evans, C., Goodare, H., Kelson, M., Kent, A., Oliver, S., Thomas, S. & Wallcraft, J. (2003). Involving the public in NHS public health, and social care research: briefing notes for researchers.: Involve.

<sup>5</sup> INVOLVE. (2012). Briefing notes for researchers: Involving the public in NHS, public health and social care research. Eastleigh: INVOLVE: p.6

relevant terminologies associated with public involvement were included in the PiiAF. We also intend the PiiAF to be relevant to people working with different approaches to involvement who want to assess its impact, so we hope that having a broad term that covers the range of people and groups that may be involved in research and approaches to involvement will minimise the likelihood of people feeling excluded by terminology.

### **QUALITATIVE RESEARCH**

An approach to research that focuses upon understanding real world situations from the point of view of the people being studied and asks questions such as 'how' or 'why'. Evidence usually consists of words (e.g. what people say, descriptions of observed events etc.).

### **QUANTITATIVE RESEARCH**

An approach to research that systematically manipulates and measures variables in order to ask 'what' and 'how many'. Evidence usually consists of numbers (e.g. health scale scores, reaction times etc.).

### **RECORD CARD**

This is a tool to capture the outcomes of explorations and discussions of the framework elements. It should be used when developing the impact assessment plan.

### **RESEARCH PROCESSES**

Research processes refers to those activities that result in research being carried out. For example collecting data is an example of a research process.

### **RESEARCH FOCUS**

The research focus refers to all aspects of research including the discipline within which the research is being carried out, the research topic, question and design. It also includes the population for the research and the project team.

### **RESOURCES**

Resources are those aspects of the physical context that can be used to support PI such as funding and training.

### **SERVICE USERS**

Service users are people who use health or social services.

### **STAKEHOLDERS**

Stakeholders are all the people who have an interest in the research including research participants, funding organisations, and policy-makers as well as members of the public-involved and academic researchers.

### **STUDY DESIGN**

The study design is the plan for the research including the ways in which research methods will be used in order to answer the research question. An example of a study design is a randomised controlled trial.

**VALUES**

The established collective principles and accepted standards of a person or a social group. In the PiiAF values are presented as underpinning approaches to PI and influencing PI processes and impacts.

**VARIABLES**

Anything (property, characteristic, attribute) that can vary or that can be varied e.g. age, gender or number of goldfish owned. Variables are usually found in quantitative research where one variable might be manipulated in order to find out how it affects another variable.

## *Annex 4: Further Reading – work in progress*

### **Reviews and overviews published since 2009 of public involvement and impact assessment**

Barber, R., Boote, J. D., Parry, G. D., Cooper, C. L., Yeeles, P., & Cook, S. (2012). Can the impact of public involvement on research be evaluated? A mixed methods study. *Health Expectations*, 15(3), 229-241. doi: 10.1111/j.1369-7625.2010.00660.x

Brett, J., Staniszewska, S., Mockford, C., Seers, K., Herron-Marx, S., & Bayliss, H. (2010). *The PIRICOM Study: A systematic review of the conceptualisation, measurement, impact and outcomes of patients and public involvement in health and social care research*. University of Warwick: University of Warwick.

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Nilsen, E., Myrhaug, H., Johansen, M., Oliver, S., & Oxman, A. (2010). *Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material*. Cochrane Database of Systematic Reviews.

Staley, K. (2009). *Exploring impact: Public involvement in NHS, public health and social care research*. Eastleigh: INVOLVE.

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Staniszewska, S. (2009). Patient and public involvement in health services and health research: A brief overview of evidence, policy and activity. *Journal of Research in Nursing*, 14(4), 295-298. doi: 10.1177/1744987109106811

### **Further reading on issues associated with public involvement and assessing impact**

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Gibson, A., Britten, N., & Lynch, J. (2012). Theoretical directions for an emancipatory concept of patient and public involvement. *Health (London, England: 1997)*, 16(5), 531-547. doi: 10.1177/1363459312438563

Glasby, J., & Beresford, P. (2006). Who knows best? Evidence-based practice and the service user contribution. [Article]. *Critical Social Policy*, 26(1), 268-284. doi: 10.1177/0261018306059775

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Tritter, J. Q., & McCallum, A. (2006). The snakes and ladders of user involvement: moving beyond Arnstein. *Health Policy*, 76(2), 156-168.

### **Further reading on complex interventions and assessment approaches**

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Staley, K., Buckland, S., Hayes, H., & Tarpey, M. (2012). 'The Missing Links': Understanding How Context and Mechanism Influence the Impact of Public Involvement in Research. *Health Expectations*. doi: 10.1111/hex.12017

### **Further reading on good practice in public involvement and public involvement reporting published since 2009**

INVOLVE. (2012). Briefing notes for researchers: Involving the public in NHS, public health and social care research. Eastleigh: INVOLVE.

Staniszewska, S., Brett, J., Mockford, C., & Barber, R. (2011). The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. *International Journal of Technology Assessment In Health Care*, 27(4), 391-399.

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Beresford, P. (2009). Chapter 13: Control. In J. Wallcraft, B. Schrank & M. Amering (Eds.), *Handbook of Service User Involvement in Mental Health Research* (pp. 181-199). Chichester: John Wiley & Sons.

Beresford, P., & Rose, D. (2009). Chapter 2 - Background. In A. Sweeney, P. Beresford, A. Faulkner, M. Nettle & D. Rose (Eds.), *This is Survivor Research* (pp. 11-21). Ross-on-Wye: PCCS Books.

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Ferguson, I. (2007). Chapter 7 - Concluding Thoughts: Frustrations and Possibilities. In M. McPhail (Ed.), *Service user and carer involvement : beyond good intentions*. Edinburgh: Dunedin Academic.

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