

## **Appendix 1: Public and Patient Involvement (PPI) in Research Guidelines**

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## Appendix 1: Public and Patient Involvement (PPI) in Research Guidelines

**Please note:** This document is intended for researchers planning to submit applications to an Irish Cancer Society research grant. For general information regarding the Irish Cancer Society's Public and Patient Involvement, please contact [ppi@irishcancer.ie](mailto:ppi@irishcancer.ie)

### 1. What is Public and Patient Involvement in research?

The Irish Cancer Society is committed to putting patients, families, survivors, supporters and the public at the very heart of what we do. In keeping with this commitment, we are working to embed Patient and Public Involvement (PPI) in our research processes. PPI can be contextualised in the many different ways people with cancer can interact with research, specifically by means of *participation*, *engagement*, and *involvement*<sup>1</sup>.

#### Participation

A person with cancer may be recruited into, and take part in, a research study and provide data of some form.

#### Engagement

Engagement is when the researcher communicates and disseminates research information, for example, at science festivals, public talks, television programmes, or radio.

#### Involvement

Involvement is distinct from participation or engagement. Where participation and engagement are conducted 'to', 'about', and 'for' people with cancer, involvement is conducted 'with' or 'by' people

with cancer. People with cancer can be involved at any stage of the research process, from conceptualisation to dissemination.

## 2. Why is PPI important?

PPI is becoming increasingly common in research. The Irish Cancer Society is committed to expanding the involvement of those affected by cancer in the research that the Society funds, and in the funding decision-making process. This commitment is reinforced by the Irish Governments' National Cancer Strategy (2017-2026)<sup>2</sup>, which highlighted:

*“Patient involvement in cancer research improves the relevance of research questions, the quality, acceptability and feasibility of research conduct and the likelihood of uptake of research outputs.”*

PPI creates a partnership between people affected by cancer and researchers. It is more than a tokenistic gesture to comply with policy, but can provide a real and substantial benefit to all key stakeholders. While not without its challenges, PPI can:

- Promote a sense of empowerment and value among patients<sup>3</sup>
- Enhance patient trust in researchers<sup>3</sup>
- Improve researchers' insight into their own research area<sup>3</sup>
- Help researchers identify barriers and come up with solutions to research<sup>3</sup>
- Increase trust and acceptability in the patient community of research findings<sup>3</sup>
- Inform the provision, access, and location of healthcare services<sup>4</sup>
- Improve the dialogue between healthcare professionals and patients<sup>4</sup>

Specific to the cancer setting, PPI may be used by patients as a resource, to make sense of living with chronic condition<sup>5</sup>. People with cancer report feeling enhanced knowledge and skills from taking part in PPI, as well as feeling they contributed to research by providing a lay perspective (i.e., practical knowledge about being a patient with cancer)<sup>6</sup>.

As such, PPI can be a valuable tool in the research process for both patients and researchers, and the Irish Cancer Society aims to expand its PPI work over the coming years.

### 3. PPI and the funding process

The Irish Cancer Society aims to embed PPI in its grant review process and funding decisions. As such, the selection of award recipients is co-decided by scientific and patient reviewers. In doing so, the research we fund is of the highest scientific quality, while being relevant and important to people affected by cancer.

As the ultimate stakeholders in any future improvements of cancer care, advances in cancer research is of the most impact to patients. The Irish Cancer Society, therefore, encourages all applicants to use the PPI sections as an opportunity to connect with the patient reviewers. To do this, it is vital that application form sections allocated to patient reviewers are written in plain, non-technical language.

#### 3.1. Lay Summary

A lay summary should provide a brief overview of the research proposal, written in a format appropriate and understandable to your audience. Remember, your audience, who will be patients, **may not** have a scientific background. Therefore, ensure the lay summary is written in plain English (please see Section 5). However, an important consideration when writing a lay abstract is to determine the right balance between pitching it to the correct lay audience and oversimplifying it too much. As such, the abstract should be written in clear plain English, but also adequately conveys the research question and what makes that particular research project important. The abstract may still have some “jargon” or scientific names when necessary, once they are clearly defined in understandable terms.

Please see below for sample answers for the Lay Summary Section:

**Example 1: Technical language used. Poor abstract with very little context. Please note, the project described in this example has been created for the purpose of providing guidelines.**

Background of the research proposal:

Our group was the first group to establish and publish research on Trastuzumab-resistant cell line variants. At present, to our knowledge, we are the only group researching the role of Hypoxia-inducible factor 1-alpha (HIF-1 $\alpha$ ) in Trastuzumab drug resistance in HER2+ breast cancer. This is a very interesting area that we have been researching. This research may also be beneficial in other HER2 targeted therapies.

Overall problem:

The focus of this project is on a drug called Trastuzumab. The problem that we are addressing is Trastuzumab drug resistance. The question we are asking is why do some patients respond to Trastuzumab treatment and why do some patients not respond to Trastuzumab treatment?

Trastuzumab is a monoclonal antibody that prevents HER2-mediated signalling. Trastuzumab is approved for the treatment of HER2-positive breast cancer. Trastuzumab is showing promise in the clinic but, like most therapies, the issue of innate and *de novo* resistance prevails. Our research focuses on investigating the mechanisms of drug resistance, finding ways to overcome this resistance and finding predictive and/or prognostic biomarkers for this breast cancer treatment.

How are we addressing the problem of Trastuzumab resistance?

In the laboratory, we have Trastuzumab-sensitive breast cancer cell line variants and we have developed Trastuzumab-resistant breast cancer cell line variants. We are comparing the proteins in drug-resistant cells to the drug-sensitive cells to try to find statistically significant differences between the two. We have identified HIF-1 $\alpha$  as a potential protein involved in the mechanism of Trastuzumab resistance.

What is HIF-1 $\alpha$  and what are our next steps?

HIF-1 $\alpha$  is one of the major transcription factors that regulates tissue response to low oxygen tension. HIF heterodimers bind to hypoxic response elements (HREs) in the genome, this results in activation of pathways involved in angiogenesis, pH regulation, metabolism and apoptosis.

We have shown in the laboratory that increased expression of HIF-1 $\alpha$  directly correlates with increased resistance to Trastuzumab treatment. We are interested in further investigating if HIF-1 $\alpha$  plays a role in initiating and/or promoting Trastuzumab drug resistance. If awarded this grant, we will have the opportunity to expand this research and to test these findings in other breast cancer models.

**Example 2: Understandable lay abstract with good level of research context given. Plain language used. Please note, the project described in this example has been created for the purpose of providing guidelines.**

Overall problem:

Trastuzumab is a drug used to treat a certain type of breast cancer called HER2+ breast cancer. This drug has been very successful in treating breast cancer. However, unfortunately, while Trastuzumab destroys a lot of breast cancer cells, there are some cancer cells that can still stay alive. When treatment does **not kill all cancer cells**, this is called **drug resistance**.

Background of the research proposal:

With the issue of Trastuzumab drug resistance in mind, we previously developed two types of breast cancer cells in the laboratory that represent the different ways that patients respond to Trastuzumab. One type being cells that die after Trastuzumab treatment and the other type are cells that do not die after Trastuzumab treatment. We previously compared hundreds of different ingredients in these two different types of cells. We found one particular ingredient that we believe to be involved in stopping Trastuzumab working.

#### What is the specific ingredient?

We found that the breast cancer cells that are resistant to Trastuzumab treatment are the only ones that **produce large amounts of the “Hypoxia-inducible factor-1-alpha (HIF-1 $\alpha$ )”** ingredient. We need to see if HIF-1 $\alpha$  is the “brains-of-the-operation” when it comes to Trastuzumab resistance.

#### What is HIF-1 $\alpha$ ?

Tumours can grow very fast, but, sometimes the walls surrounding the tumour cannot grow at the same speed and are faulty. Because of this, the tumours can become patchy and “leaky”. When this happens, oxygen can leak out of the tumour causing the conditions in the tumour and nearby area to become very harsh and unfavourable. But, cancer cells cleverly find ways to avoid the harsh conditions and they can become stronger and survive better. Cancer cells use HIF-1 $\alpha$  to make these unfavourable conditions within a tumour less harsh.

#### How are we addressing this problem?

Our **next steps** are to find out why the resistant cells are producing large amounts of HIF-1 $\alpha$ . We believe that Trastuzumab will work again if we stop the cells producing large amounts of this specific ingredient. We will test different drugs to shutdown HIF-1 $\alpha$  in the resistant cells. When we find the best drug to shut down HIF-1 $\alpha$  we will then test Trastuzumab’s ability to kill the cells. If Trastuzumab works again we will test the two drugs together to see if they work better together as a “**double therapy**”. The next step will be to try the two drugs in mouse models of HER2 breast cancer. Mice with resistant cancer tumours will be given either Trastuzumab alone or the two drugs together to see if the “double therapy” works best.

Our research will focus on trying to stop drug resistance occurring in patients in the first place and to try and make Trastuzumab better at treating breast cancer.

### **3.2. Impact**

Broadly speaking impact is the demonstrable contribution that research makes to society. Impact is defined as research being used to bring about a positive change to the lives of people affected by cancer. The impact research has is specific to each project and therefore, impact is varied and can occur over different timescales, from the short to long term.

Some of the key areas of research impact include:

- academic impact
- health and health systems/services impact
- health-related and societal impact
- influence on policy making
- economic impact

**It is vital that applicants describe their research project honestly, and do not overstate the impact of a research project. Rather, goals should be realistic, as should the *potential* impact that the project can have.**

It is recognised that for some research there will be no direct impact on the lives of people affected by cancer in the short or medium term. However, the research will contribute to a wider conversation on cancer with the view to eventually directly impacting the lives of people affected by cancer.

The inclusion of academic impact is also an important consideration when measuring research impact, as it demonstrates the contribution that a particular research project has made towards the advancement of science, and to the cancer research knowledgebase. These academic advances can be measured in terms of primary research related outputs and includes research publications, knowledge dissemination, capacity building, and collaborations.

Please note, when communicating the impact of your research, it is also useful to identify and articulate the different routes to impact - which are the means by which you aim for your research to be impactful.

### ***3.3. Sharing of research findings***

The Irish Cancer Society is the largest voluntary funder of cancer research in Ireland. Research is conducted primarily for the benefit of patients, therefore, a key priority of the Irish Cancer Society is to ensure that the public (including people affected by cancer) are kept up to date on research that is funded by the Society. In line with this, it is a requirement that all applicants produce a dissemination plan to include communication of their research to all relevant audiences (including the public).

It is important to note that while peer-reviewed journals are an important means of communicating research findings to academic researchers, members of the public are less likely to access academic journals.

Research dissemination and knowledge exchange includes:

- Public engagement talks or events e.g., Irish Cancer Society ‘Decoding Cancer’, Pint of Science, Science Week events, public university talks, etc.;
- Non-peer reviewed professional periodicals e.g., The Irish Psychologist, World of Irish Nursing;
- Newspapers/media e.g., The Irish Times, thejournal.ie, Newstalk;
- Blog posts e.g., professional blog, Irish Cancer Society website;
- Peer-reviewed journals (open-access).

#### 4. Patient involvement plan

Involvement can be incorporated into almost any stage of the research process, which should be planned from the very beginning of study design. Examples of how patient involvement can be incorporated into research includes (but is not limited to):

- as members of a patient advisory group for the project;\*
- commenting on and developing patient information leaflets, consent forms, questionnaires or other research materials;
- user and/or carer researchers carrying out the research;
- commenting on and developing dissemination materials (e.g., conference abstracts, posters, presentations);
- Involvement in organising and running public and patient engagement activities.

In general, when, where, and how involvement will be included in studies should be decided early in the research process. The patient involvement plan must detail activities that will be organised during the project.

Please note, a number of universities within the Republic of Ireland already have dedicated individuals, infrastructure, training, or programmes (e.g., the HRB 'PPI Ignite Award') in place dedicated to PPI. We recommend that you engage with these local resources when planning how patient involvement will be integrated into your project.

*\*Any post-award significant alterations to study design or protocol suggested by the patient advisory group would need to be approved in advance by the Irish Cancer Society throughout the duration of the research project.*

##### **4.1. Budgeting for PPI**

The cost of PPI is dependent on how you plan to embed it into your study i.e., your 'Patient involvement plan'. As such, it is difficult to prescribe guidelines on how to budget for PPI. However, **at a minimum, it is expected that the cost to patient members associated with involvement are covered by the research grant** e.g., bus/train fares, mileage, parking charges, and subsistence (if appropriate).

The steps to budgeting are described below:



Step	Activity
Step 1: Framework selection	Select a framework for mapping involvement costs. This might be the research project cycle (i.e., the step-by-step research process/procedure) or a project timeline (e.g., Gantt chart).
Step 2: Planning your involvement	Make a plan of the involvement activities you intend to incorporate into your research.
Step 3: What are the costs?	For each activity, identify the specific costs for which you will need to budget.
Step 4: How much will it cost?	Estimate the cost or range of costs against each involvement activity.  To work out the budget for your study, go to the online cost calculator: <a href="https://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/">https://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/</a> . Please note the online calculator is in Pound Sterling.
Step 5: Mapping	Map the involvement activities onto your selected project framework so that you know exactly when in the project timeline costs are allocated.

*Adapted from the UK National Institute for Health Research, Budgeting for Involvement (2013)*

An online calculator is available on the *NIHR Involve* website: <https://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator>. Please note the online calculator is in pound sterling (£), euro conversion rates will apply. The online calculator is a guiding tool, all costs must be appropriate to costings in the Republic of Ireland and all researchers must verify the costs associated with their patient involvement plan. Please check that the host institute has appropriate systems in place for the payment of PPI costs and expenses. Costings from all categories of the online calculator will be eligible (see below). However, please note that final approval of all costs is at the discretion of the Irish Cancer Society.

Please see the worked costing example below for guidance on creating and budgeting for the patient involvement plan.

**PPI budgeting costs:**

<b>Costing category</b>	<b>Related costs</b>
Payments and rewards	<ul style="list-style-type: none"><li>• Fees to individuals</li><li>• Vouchers/tokens for individuals</li><li>• Prize draw awards</li><li>• Fee/donation to a group</li><li>• Funding for additional training and learning</li><li>• Honorary appointment e.g., lay fellow or research partner</li></ul>
Expenses	<ul style="list-style-type: none"><li>• Travel</li><li>• Subsistence</li><li>• Childcare</li><li>• Carer costs</li><li>• Personal assistants</li><li>• Overnight accommodation</li><li>• Home office costs</li></ul>
Involvement activity	<ul style="list-style-type: none"><li>• Finding people/advertising</li><li>• Training and learning costs</li><li>• Venues and catering</li><li>• Equipment and books</li><li>• Access to university facilities</li><li>• Conference fees</li></ul>
Involvement staffing	<ul style="list-style-type: none"><li>• Administrative support</li><li>• Involvement coordinator</li><li>• Independent facilitator</li><li>• Peer researchers/interviewers</li></ul>
Other costs	<ul style="list-style-type: none"><li>• Disclosure and barring service</li><li>• Language translation and interpretation costs</li><li>• Support for people with impairments</li></ul>

*Adapted from the UK National Institute for Health Research, Involvement Cost Calculator*

**Worked costing example:** A researcher wishes to set up a patient advisory group to guide the dissemination of findings. The aim is to ensure the research findings are communicated as widely and efficiently as possible, are accessible to a lay audience, and are engaging to the general public. To achieve this aim, the researcher hopes to host a public engagement event.

The researcher is looking for five patient advocates to form the advisory group. The group will meet for a half day workshop to design the public engagement event, creating information booklets, and

educational project posters. All information booklets and educational videos will be accessible on the researcher's website.

*The estimated costs associated with setting up the advisory group and the costs associated with the public event are as follows:*

Category	Detail	Quantity	Cost	Total
Travel	Local travel in Dublin	3	€7	€21
	Travel from outside of Dublin	2	€30	€60
Focus group payment	Payment for attending focus group/workshop	5	€100	€500
Venue costs	University meeting room cost	1	€0	€0
Catering costs	Breakfast and lunch for attendees (€10 per person/per meal)	5	€20	€100
Advertising	Newspaper advertisement (for 2 weeks)	1	€70	€70
Dissemination	Printing of 12-page booklets	250	€0.96	€240
	And educational posters:	5	€32	€160
Public Event costs	Costs for university venue (1/2 day)	1	€150	€150
	Catering (tea and biscuits) (€3.50 per person)	100	€3.50	€350
<b>TOTAL COST (€1000 from PPI budget and €651 from consumables budget)</b>				<b>€1,651</b>

*All costs were calculated using estimated costs for train tickets, hotels, and so on in the Republic of Ireland as of March 2019.*

## 5. Writing in plain English

There are many online resources available to guide you in writing an effective plain English summary. Some of these resources are listed in Section 6 of this document.

*Here are some general notes on how to write in plain English:*

- Patients are not scientists (usually) and knowledge should not be assumed. Avoid using technical language or scientific terminology. Use everyday words to communicate your point and explain the science. While language should be understandable, it should not be dumbed

down - It may be necessary to use scientific words and jargon in order to convey why your research is special, but be sure to explain it thoroughly and be consistent in its use.

- Use short clear sentences.
- Use paragraphs
- Use an active voice, and place the person/group/thing doing the action at the beginning e.g., 'We ran an experiment,' rather than, 'The experiment was run.'
- Don't use 'don't'. You can write in plain English without becoming too casual/unprofessional.
- Use an appropriate tone. This is not a newspaper article, and its purpose is not to entertain.
- Make sure grammar, punctuation, and spelling are accurate.
- Bullet points (like these ones) can make it easy to digest a lot of information

## 6. Additional Resources

### General resources

- INVOLVE – UK National Institute of Health Research (NIHR) initiative to support PPI.  
<http://www.invo.org.uk>
- National Standards for Public Involvement.  
<https://www.invo.org.uk/posttypepublication/national-standards-for-public-involvement/>
- NALA (National Adult Literacy Agency)  
<https://www.nala.ie>
- Access to Understanding: Promoting public understanding of biomedical and health research  
<http://www.access2understanding.org>

### Writing a Lay Summary

- Duke, M. (2012). How to write a lay summary.  
<http://www.dcc.ac.uk/sites/default/files/documents/publications/HowToLaySummariesDec2012.pdf>

### Communicating to patients

- NHS England. Language Matters: Language and Diabetes.

<https://www.england.nhs.uk/wp-content/uploads/2018/06/language-matters.pdf>

### Writing in plain English

- NALA (National Adult Literacy Agency). *Writing and Design Tips*.  
[https://www.nala.ie/sites/default/files/publications/Writing%20and%20Design%20Tips%202011\\_1.pdf](https://www.nala.ie/sites/default/files/publications/Writing%20and%20Design%20Tips%202011_1.pdf)

### Budgeting for PPI

- INVOLVE PPI Involvement Cost Calculator  
<https://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/>

## 7. References

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- 6) Froggatt, K., Preston, N., Turner, M., & Kerr, C. (2014). Patient and public involvement in research and the Cancer Experiences Collaborative: benefits and challenges. *BMJ Supportive & P Care*, 5, 518–521.