General Guidelines for Applicants

Smoking Cessation in Cancer Patients 2019 - Research Project Grant

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

<table>
<thead>
<tr>
<th>Key Dates</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10 July 2019</td>
<td>Applications open</td>
</tr>
<tr>
<td>EXTENDED: 09 Sept 2019 – 3pm</td>
<td>Application Deadline</td>
</tr>
<tr>
<td>September/October 2019</td>
<td>Review</td>
</tr>
<tr>
<td>October 2019</td>
<td>Awardee selected</td>
</tr>
</tbody>
</table>

Please note: that the above dates are subject to change at the discretion of the Irish Cancer Society.
General Guidelines for Applicants

Smoking Cessation in Cancer Patients 2019 - Research Project Grant

1. Introduction

1.1. Overview

The purpose of this award is to fund a focused research project examining the provision of a smoking cessation programme for patients with cancer which would be delivered as part of routine clinical care. The Smoking Cessation in Cancer Patients Grant will provide funding of up to €65,000 for a project of up to a maximum of 18 months duration.

1.2. Background

Smoking is a leading cause of preventable mortality in Ireland resulting in approximately 5,950 deaths in 2018\(^1\), approximately half of which are cancer deaths. Continued smoking after a cancer diagnosis results in adverse health outcomes and increased mortality\(^2\), and may be associated with poorer response to treatment, increased treatment-related toxicity, and poorer health-related quality of life\(^3\).

Conversely, research has also shown that smoking cessation after diagnosis can result in improvements in survival, treatment efficacy, and outcome\(^2\). This is recognised in the National Cancer Strategy (2017-2026)\(^4\), which recommends that “smokers should be given appropriate smoking cessation supports as part of their treatment regime and care planning”.

The Health Service Executive (HSE) currently offer a number of cessation programmes, from brief to intensive interventions, with the delivery varying from online to face-to-face. The HSE’s National Standard for Tobacco Cessation Support Programme\(^5\) provides a framework for intensive behavioural intervention.
However, international evidence suggests that discussion of tobacco use and cessation services are not routinely offered to patients within healthcare services, despite recognition of its importance\textsuperscript{6,7}. Additionally, HSE cessation programmes are not disease- or time-specific and it is unknown how routinely or consistently cessation interventions are being offered to patients with cancer. When the service is offered, rates of uptake and attendance are unclear.

Therefore, the aim of this award is to fund a scoping study regarding the provision of a smoking cessation intervention for cancer patients in Ireland.

1.3. The intervention model

Evidence suggests that behavioural interventions (i.e., Motivational Interviewing\textsuperscript{8}) are most effective in increasing rates of long duration smoking cessation when they are hospital-based, high-intensity, and occur peri-treatment. This is particularly true when behavioural intervention is combined with Nicotine Replacement Therapy\textsuperscript{9,10}.

As such, multidisciplinary teams in designated Cancer Centres and public hospital cancer services may be best placed to deliver evidence-based smoking cessation programmes as part of routine clinical care. Such a model is currently undergoing an extensive randomised controlled trial elsewhere\textsuperscript{11}.

1.4. Purpose

This award will fund a scoping study examining the intervention model outlined in Section 1.3., i.e., the provision of a hospital-based, high-intensity, peri-treatment behavioural smoking cessation programme as part of routine clinical care for patients with cancer.

The programme of research should be designed to take account of existing national smoking guidelines and frameworks (e.g., National Standard for Tobacco Cessation Support Programme) and infrastructures (e.g., designated Cancer Centres). Applications for the Smoking Cessation in Cancer Patients Grant must, at a minimum, address the following questions:

**Required Research Questions:**

- What is the prevalence of smoking among cancer patients in Ireland?
- What is the uptake of smoking cessation services among cancer patients and what are the current referral pathways to such services?
- What smoking cessation services are currently being offered to patients as part of routine clinical care?

Preference will be given to applications which also address the following research question:
**Desired Research Question:**

- What is the feasibility* of the smoking cessation programme outlined in Section 1.3. (from all relevant stakeholder perspectives) taking into consideration existing national smoking guidelines, frameworks, and infrastructure?

*An important initial step in complex intervention development is to evaluate the feasibility of a programme. Feasibility studies examine, for instance: intervention acceptability; intervention demand; implementation methods; practicalities; and intervention adaptation requirements (see, for example, Bowen et al., 2009[1]; and the MRC Guidelines on complex intervention development[13]).

**1.5. Funding**

It is the intention of the Irish Cancer Society to provide funding for one grant in 2019, subject to grant proposals meeting the required standard as assessed by international peer review. The Smoking Cessation in Cancer Patients Grant will provide funding of up to €65,000 for a project of up to a maximum of 18 months duration.

**1.6. References**


**2. Eligibility Criteria**

**2.1. Applicant Eligibility**

Applications from individuals that do not meet the eligibility criteria will not be assessed. We therefore strongly recommend you read the following requirements carefully. If you are unsure of your eligibility, please contact grants@irishcancer.ie.

Applicants must have:

- a doctoral degree by research (or equivalent*) in a relevant field
- two or more years post-doctoral research experience

*PhD equivalent is defined as three or more senior (first, joint-first, or last) author publications in peer-reviewed academic journals or 4 years full time research experience. Alternative research outputs may be considered eligible e.g., monographs. If you do not meet the minimum eligibility criteria, but feel you possess the appropriate experience/qualifications, please contact grants@irishcancer.ie in the first instance.

**2.2. Project Eligibility**

As this is a focused research call, applicants are required, at a minimum, to address the research questions outlined in section 1.4. There are no stipulations as to how these questions are answered. However, applications will be subjected to expert peer review which will evaluate how robustly the proposed methodology will answer the specified research questions. Please see section 6.2 for details of the evaluation criteria.
2.3. Host institution

The host institution is the organisation that receives and administers grant funding and is responsible for compliance with all general and specific terms and conditions of awards. In order to be eligible to apply for funding, a proposed host institution must be a higher education institution in the Republic of Ireland and must be one of the HRB’s approved host institutions: https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions.

2.4. Stakeholder Steering Group

The Irish Cancer Society is committed to ensuring representation from key stakeholders in helping to guide and shape how best to deliver continued improvements in patient outcomes. In particular, the Irish Cancer Society is dedicated to putting patients, families, survivors, supporters, and the public at the very heart of what we do.

It is therefore a requirement of this award that provision for a Stakeholder Steering Group be included as part of this project proposal. Such a group may be consulted throughout the duration of the proposed project to inform on key methodologies such as stakeholder recruitment, design of materials (e.g., questionnaires/interview scripts), interpretation of results, and advice on dissemination plans across the various stakeholder networks. At a minimum, it is expected that two patient representatives and appropriate representatives from the HSE will sit on the steering/advisory group.

3. Application Procedure

3.1. How to Apply

Applications must be completed and submitted through the Irish Cancer Society Gateway Grant Tracker online system. In order to submit an online application you are required to register at the following address: https://grants.cancer.ie.

3.2. Overview of the Application Process

When you enter your login details you will be directed to the Portal Home page. From here you can:

- Update your basic information (please make sure all fields are completed)
- Make a new grant application
- Access previous grant applications
3.3. Making an application

When you have ensured that all your basic details are entered then you can proceed to apply for a new grant application. This can be done by returning to the Portal Home page and clicking to apply for funding from one of our grant streams. Or alternatively through the ‘My Applications’ tab on the left hand side of the page, and clicking the ‘New Application’ button.

You will then be asked what Grant Type you would like to apply for. Click ‘Apply’ for the Grant Type detailed as ‘Smoking Cessation in Cancer Patients Grant 2019’.

4. The Application Form

There are 9 sections outlined on the left hand side of the page:

a) Introduction
b) Project Outline
c) Research Programme
d) Lead Applicants’ Curriculum Vitae
e) Co-Applicants/Collaborators
f) Declaration of Support
g) Budget
h) Lay Research Pitch*
i) Validation summary

These sections are to be viewed and completed. It is recommended that you save the information as you complete each section. This can be done by clicking ‘Save’ as you go along. Alternatively the information will be saved when you click ‘Save and Close’. By clicking ‘Previous’ you will be brought to the previous section and by clicking ‘Next’ you will be brought to the next section.

As you proceed through the sections you will see a small blue question mark icon next to some of the sections. By clicking on this icon you will get more information on the section to be completed.

Sections that are required to be filled out have a red circle icon next to them. You will not be able to proceed with the application if these sections are not completed.
*Note: External patient representatives will appraise the sections marked by an asterisk. It is very important that these sections are written in plain English and are accessible to a non-scientific audience. Please see information from the Irish Cancer Society on Public and Patient Involvement (PPI) in Research Guidelines (Appendix 1) for more information.

a) Introduction
This section gives the overview information of the Smoking Cessation in Cancer Patients Grant.

b) Project Outline
Details of your application are entered into this section. Input and save the information as required under the following headings:

- Proposed title
- Proposed start date (must not be before December 2019)
- Duration (12-18 months)
- Applicant details
- Proposed host institution
- Proposed research sites
- Cancer type
- Research type
- Discipline

c) Research Programme

Basis for research: Please describe the previous research which forms the basis of your research proposal. You may include research carried out by the applicants’ research team (400 words max).

Hypothesis, research questions, and/or aims: Please outline the hypothesis, research questions, and/or aims of your research proposal. Please also ensure that the aims are realistic and achievable in the time frame (250 words max).

Methodology: Please describe and justify the methods, procedures, and experimental design you will use to conduct your research (1000 words max).

For quantitative research, please provide statistical analysis for each part of your experimental plan; power calculations, numbers of samples, number of matched controls, and strategy of different controls to be used should all be discussed. Additionally, please discuss the feasibility of obtaining/accessing sufficient numbers of patient participants and controls that will result in statistically meaningful results.

For qualitative research, please describe the planned sample size and rationale, data collection methodologies (e.g., interviews, focus groups, and transcription procedures), analytic framework(s),
and sources of bias. Additionally, please discuss the methodology and feasibility of recruiting the planned sample size.

**Knowledge Outcomes/Deliverables:** Please clearly describe what knowledge will be gained through the proposed programme of work, and how your proposed study will answer the required research questions outlined in section 1.4. *(400 words max).*

**Stakeholder Steering Group Plan:** Please outline your plan for incorporating a Stakeholder Steering Group into your research programme *(400 words max).* The Stakeholder Steering Group is a requirement of grant funding. At a minimum, it is expected that two patient representatives and appropriate representatives from the HSE will sit on the Stakeholder Steering Group. The Society asks that all applicants carefully read Appendix 1 of these guidelines, which provides general guidance on public and patient involvement. Any plan which includes *participation* or *engagement* activities in lieu of *involvement* will not be funded. When responding to this questions, please address the following:

- What key stakeholders will be approached and from where?
- What aspects (e.g., recruitment, assessment, dissemination) of the proposed research will include the Stakeholder Steering Group?
- What is the procedure for integrating the Stakeholder Steering Group into these aspects?
- What steps will be taken to ensure that the input of the Stakeholder Steering Group is not tokenistic?

**Ethical Considerations and Data Protection:** Please describe relevant ethical considerations for this project, including: Potential risks of participation and how they will be minimised, Research Ethics Committee application procedures, data protection considerations with respect to GDPR legislation, etc. *(200 words max).*

**References:** Please cite any literature referenced in the sections above.

**Gantt Chart and Research Images:** You must upload a Gantt chart for the proposed research study. You may upload up to four additional research images. All uploads must be in PDF format. Please ensure that figures are legible when uploading. Illegible figures may be difficult for the peer review panel to assess and could detract from your application.

**d) Lead Applicant Curriculum Vitae**

In this section you are required to upload your CV. Please use the CV template downloadable from this section of the website. To upload the CV click ‘Attach’ then locate the file to be attached, then click ‘Attach’.

**e) Co-Applicants/Collaborators**

Each application will have single lead applicant who will take overall responsibility for the project.
You may add up to 5 Co-Applicants to the project. Co-Applicants must have a well-defined and substantial role in the proposed plan e.g., substantial input into study design, data collection, or analysis and interpretation. Co-Applicants are required to confirm their participation and approve the application prior to it being submitted.

Individuals or organisations that provide assistance on limited aspects of the research, for example, providing access to participants, do not qualify as a Co-Applicant. Such individuals or organisations can be listed as Collaborators. Collaborators do not need to confirm participation or approve the application.

**f) Declarations of Support**

Please upload a declaration of support letter from the head of department at your host institution. The declaration of support template is downloadable from this section on the online system. Letters of support should be written on headed paper and signed. To upload this letter of support click ‘Attach’, locate the file to be attached and then click ‘Attach’. If your research will take place at any additional sites (e.g., public hospital), you must upload a declaration of support from a relevant person within this organisation.

**g) Budget**

A full detailed breakdown of costs and justification for all costs must be provided for each budget heading in your application.

Funds may be requested for the following:

<table>
<thead>
<tr>
<th>i. Salary costs</th>
<th>All salary costs and staff should be detailed and justified, with costs calculated using the appropriate HSE or IUA scales and inclusive of employer PRSI and appropriate pension contributions.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HSE: <a href="https://www.hse.ie/eng/staff/benefitservices/pay">https://www.hse.ie/eng/staff/benefitservices/pay</a></td>
</tr>
<tr>
<td></td>
<td>IUA: <a href="https://www.iua.ie/research-innovation/researcher-salary-scales/">https://www.iua.ie/research-innovation/researcher-salary-scales/</a></td>
</tr>
<tr>
<td>ii. Consumables</td>
<td>Please allow sufficient budget for all materials and consumables required to carry out your research proposal.</td>
</tr>
<tr>
<td>iii. Travel and dissemination costs</td>
<td>Please detail the dissemination costs for the research study e.g. printing, posters, publication costs, and public awareness lectures/engagement events.</td>
</tr>
<tr>
<td>iv. Stakeholder Steering Group</td>
<td>Please also detail costs associated with the lead applicants or research staff attending academic meetings and conferences e.g., registration fees, travel, accommodation.</td>
</tr>
</tbody>
</table>

Please describe costs associated with your Stakeholder Steering Group plan. This is a requirement of the Smoking Cessation in Cancer Patients Grant. 
Guidelines on Public and Patient Involvement, including budgeting, are included as an appendix to this guidance document.

**h) Lay Research Pitch**

The lay research pitch consists of four sections: Lay Summary, Steering/Advisory Committee Plan, and Sharing of Findings. Details on each section can be found below. Please note that patient reviewers will appraise these sections and it is very important that these sections are written in plain English and are understandable to a non-scientific audience.

We recommend that you carefully read the Irish Cancer Society Guidelines on Public and Patient Involvement (PPI) in Research (Appendix 1).

**Lay Research Pitch: Lay Summary:**
Please briefly detail the following *(500 words max):*
- Outline the background of your research proposal.
- Describe the methodology you plan to use for your study.
- Describe how your study will answer the questions outlined in Section 1.4.

**Lay Research Pitch: Stakeholder Steering Group Plan:**
Please note: The response to this question may be copied directly from the ‘Stakeholder Steering Group’ question of the Research Programme (application form Section C), provided it is written in plain accessible language.

Please outline your plan for incorporating a Stakeholder Steering Group into your research programme *(400 words max).* The Stakeholder Steering Group is a requirement of grant funding. At a minimum, it is expected that two patient representatives and appropriate representatives from the HSE will sit on the Stakeholder Steering Group. The Society asks that all applicants carefully read Appendix 1 of these guidelines, which provides general guidance on public and patient involvement. Any plan which includes participation or engagement activities in lieu of involvement will not be funded. When responding to this questions, please address the following:

- What key stakeholders will be approached and from where?
- What aspects (e.g., recruitment, assessment, dissemination) of the proposed research will include the Stakeholder Steering Group?
- What is the procedure for integrating the Stakeholder Steering Group into these aspects?
- What steps will be taken to ensure that the input of the Stakeholder Steering Group is not tokenistic?

Lay Research Pitch: Sharing of Findings:
A key priority of the Irish Cancer Society is to ensure that the public (particularly people affected by cancer) are kept up to date on research that is funded. 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 and people affected by cancer).

Please describe your plan for sharing your findings. This may include printed or electronic articles, presentations, public engagement events, etc. (max 200 words).

i) Validation Summary

In this section any required fields in the application form that have not been completed will be detailed. You will not be able to submit the application until all required fields are completed.

5. Submission of the Application

Once it has been verified that all required questions are answered in the correct manner on the application then the application can be submitted.

If you have added Co-Applicants to the form, they will need to approve the application before it can be submitted.

In the Validation section of the application please click "Save and Close" and then click on the "Submit" button in the right hand side of the Application Summary page.

The application deadline is 09 September 2019 at 3pm.
6. Application Assessment

Incomplete and ineligible applications and those submitted after the deadline will not be assessed.

6.1. Overview

Applications will be reviewed by both international academic reviewers AND patient representatives. Sections of the application will be assessed in the following way:

<table>
<thead>
<tr>
<th>Patient Reviewers</th>
<th>Scientific Reviewers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application form</td>
<td></td>
</tr>
<tr>
<td>• Lay Research Pitch</td>
<td>• Research Programme</td>
</tr>
<tr>
<td>- Lay Summary</td>
<td>• Steering/Advisory Committee Plan</td>
</tr>
<tr>
<td>- Steering/Advisory Committee Plan</td>
<td>• Applicants’ CVs</td>
</tr>
<tr>
<td>- Sharing of Research Findings</td>
<td>• Declarations of Support</td>
</tr>
</tbody>
</table>

Please note, the scientific reviewers will not be assessing any of the patient review sections, and vice versa. The only exception to this is the Steering/Advisory Committee Plan, which will be reviewed by both scientific and patient reviewers. As such, it is vital that the sections reviewed by patient representatives are written in accessible plain English. Failure to do this may result in the patient representatives not being able to accurately score these sections of your application.

The budget will also be reviewed by the Irish Cancer Society to ensure that it is feasible and that all maximum limits have been adhered to. Final approval of all budgeted costs is at the discretion of the funders.

6.2. Assessment Procedure

Scientific Reviewers are asked to review each section of the application and provide a score for a) the Research Programme, b) Steering/Advisory Committee Plan, c) Applicants’ CVs, and d) Declaration of Support. These sections will be assigned scores based on the scientific merit of the proposed research and the likelihood that the proposal will deliver on the required research questions (section 1.4.), in addition to the strength of the applicants and the strength of their organizational support.

Similarly, the patient panel will review and score their respective sections, specifically a) Lay Summary, b) Steering/Advisory Committee Plan, and c) Sharing of Research Findings.

Scores from reviewers will be combined - both patient and scientific reviewers. Each patient reviewer will have an equal say (provide an equal score) as the scientific reviewers.

Applicants will be notified of the outcome by email. Feedback from the application review will be made available to candidates.
7. Application Checklist

Completed application form submitted online including the upload of:

- Applicant CV
- Gantt Chart
- Declaration of Support - Head of Department
- Declaration of Support – Additional Research Site / Clinical Site

The following must be completed ONLINE by 09 September 2019.

8. Contact

If you require assistance with the online application system or have any queries about the application, please contact the Irish Cancer Society:

Email: grants@irishcancer.ie
Telephone: +353 1 2310 583
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

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.

**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), 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
- Enhance patient trust in researchers
- Improve researchers’ insight into their own research area
- Help researchers identify barriers and come up with solutions to research
- Increase trust and acceptability in the patient community of research findings
- Inform the provision, access, and location of healthcare services
- Improve the dialogue between healthcare professionals and patients

Specific to the cancer setting, PPI may be used by patients as a resource, to make sense of living with chronic condition. 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).

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.

To accommodate PPI in the funding process, the application form comprises of sections that are reviewed by the scientific panel only and sections that are reviewed by the patient panel only.
Review sections will typically be allocated in the following way:

<table>
<thead>
<tr>
<th>Application form</th>
<th>Patient Reviewer</th>
<th>Scientific Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Lay Research Pitch</td>
<td>• Research Programme</td>
</tr>
<tr>
<td></td>
<td>- Lay summary</td>
<td>• Applicants’ CVs</td>
</tr>
<tr>
<td></td>
<td>- Public and Patient</td>
<td>• Declarations of Support</td>
</tr>
<tr>
<td></td>
<td>Involvement (PPI) Plan</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Sharing of Research</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Findings</td>
<td></td>
</tr>
</tbody>
</table>

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.

Patient reviewers will score their allocated sections and therefore significantly contribute to the funding decision-making process. Scientific and patient reviewers will have an equal vote.

### 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-1α) 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-1α as a potential protein involved in the mechanism of Trastuzumab resistance.

**What is HIF-1α and what are our next steps?**

HIF-1α 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-1α directly correlates with increased resistance to Trastuzumab treatment. We are interested in further investigating if HIF-1α 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-1α)” ingredient. We need to see if HIF-1α is the “brains-of-the-operation” when it comes to Trastuzumab resistance.

What is HIF-1α?
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-1α 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-1α. 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-1α in the resistant cells. When we find the best drug to shut down HIF-1α 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. PPI and the research process

PPI can be incorporated into almost any stage of the research process, which should be planned from the very beginning of study design. Please note that only PPI plans which include involvement will be funded. Any plan which includes participation or engagement activities in lieu of involvement will not be funded. Examples of how PPI 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 PPI will be included in studies should be decided early in the research process. The PPI plan must detail the PPI 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 PPI 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 ‘PPI 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 PPI 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 PPI budgeting are described below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: Framework selection</td>
<td>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).</td>
</tr>
<tr>
<td>Step 2: Planning your involvement</td>
<td>Make a plan of the involvement activities you intend to incorporate into your research.</td>
</tr>
<tr>
<td>Step 3: What are the costs?</td>
<td>For each activity, identify the specific costs for which you will need to budget.</td>
</tr>
<tr>
<td>Step 4: How much will it cost?</td>
<td>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.</td>
</tr>
<tr>
<td>Step 5: Mapping</td>
<td>Map the involvement activities onto your selected project framework so that you know exactly when in the project timeline costs are allocated.</td>
</tr>
</tbody>
</table>

*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/](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 costing in the Republic of Ireland and all researchers must verify the costs associated with their PPI 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 PPI plan.
**PPI budgeting costs:**

<table>
<thead>
<tr>
<th>Costing category</th>
<th>Related costs</th>
</tr>
</thead>
</table>
| Payments and rewards      | • Fees to individuals  
                          • Vouchers/tokens for individuals  
                          • Prize draw awards  
                          • Fee/donation to a group  
                          • Funding for additional training and learning  
                          • Honorary appointment e.g., lay fellow or research partner |
| Expenses                  | • Travel  
                          • Subsistence  
                          • Childcare  
                          • Carer costs  
                          • Personal assistants  
                          • Overnight accommodation  
                          • Home office costs |
| Involvement activity      | • Finding people/advertising  
                          • Training and learning costs  
                          • Venues and catering  
                          • Equipment and books  
                          • Access to university facilities  
                          • Conference fees |
| Involvement staffing      | • Administrative support  
                          • Involvement coordinator  
                          • Independent facilitator  
                          • Peer researchers/interviewers |
| Other costs               | • Disclosure and barring service  
                          • Language translation and interpretation costs  
                          • Support for people with impairments |

*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 representatives 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:

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

**TOTAL COST (€1000 from PPI budget and €651 from consumables budget)** €1,651

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
- 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


Communicating to patients

Writing in plain English

- NALA (National Adult Literacy Agency). Writing and Design Tips. 

Budgeting for PPI

- INVOLVE PPI Involvement Cost Calculator 

7. References


