Clinical Study Seed Award: Funding for Non-Regulated Interventional Studies

Guidelines for Applicants

Contents

Clinical Study Seed Award 2026:

Funding for Non-Regulated Interventional Clinical Studies

Guidelines for Applicants

1. Introduction

1.1. Overview

A key priority in the Irish Cancer Society strategy 2020-2025 is ensuring that Irish patients benefit from world-class cancer research and expertise. Central to this focus is fostering and cultivating clinical trial research to ensure that Irish cancer patients have access to excellent cancer treatment, research and leaders who will drive innovative, evidence-based improvements in patient care.

While significant progress has been made in supporting clinical research, important gaps remain in the development of investigator-led non-regulated interventional studies. Many promising interventions including but not limited to surgical, radiotherapy, diagnostic, behavioural, supportive care, rehabilitation, and healthcare delivery interventions lack dedicated resources to support their development and evaluation despite their potential to significantly improve patient outcomes and health service delivery.

In line with this the Irish Cancer Society have developed the Clinical Study Seed Award 2026: Funding for Non-Regulated Interventional Clinical Studies 'The Clinical Study Seed Award' to address this gap. Aligned with the ambitions of the National Cancer Strategy and Ireland's broader clinical research ecosystem, the award seeks to strengthen the pipeline of investigator-led non-regulated interventional studies and support the generation of evidence that can improve patient care and healthcare delivery nationally.

1.2. Indicative Timelines

Milestone	Date
Applications Open	Wednesday 29th July 2026
Application Deadline	3 pm Wednesday 23rd September 2026
Review	October 2026
Awardee Selected	November 2026

Please note, above dates are provisional and subject to change at the discretion of the Irish Cancer Society.

1.3. Purpose and Objectives

The Clinical Study Seed Award aims to support the development of innovative investigator-led non-regulated interventional clinical studies that address important questions in cancer care, survivorship, supportive care and healthcare delivery. Through focused investment in trial design, feasibility and readiness activities, the scheme will strengthen Ireland's pipeline of high-quality clinical trials and increase competitiveness for future national and international funding opportunities.

The Clinical Study Seed Award aims to:

- **support the development of high-quality non-regulated interventional cancer clinical studies**, by funding the activities required to progress promising research concepts towards trial activation and delivery;
- **increase patient access to, and participation in, non-regulated interventional cancer clinical studies** by supporting the development of research that has the potential to enhance patient accrual across the Irish cancer research landscape;
- **support the career development of researchers and healthcare professionals acting as Clinical Principal Investigators (PIs)**, enabling them to build experience in the design, leadership and delivery of investigator-led interventional research;
- **strengthen Ireland's capacity to lead innovative non-regulated cancer research**, fostering multidisciplinary collaboration and developing a pipeline of future studies aligned with national cancer research priorities.

1.4. Funding and Duration

The Irish Cancer Society will fund at least **two** awards up to a maximum contribution of **€100,000** each towards a clinical trial or study across any non-regulated interventional area (For more details on Irish Cancer Society budgeting, please see the Irish Cancer Society Budgeting and Expenses Guidelines as part of **Appendix 2**).

2. Eligibility

2.1. Applicant Eligibility

Applications from lead applicants who do not meet the eligibility criteria will not be assessed. Eligible applicants include medical doctors, dentists, nurses, and allied health and social care professionals.

Lead applicants must:

- Be registered with a relevant, professional body e.g. Irish Medical Council, Irish Nurses & Midwifery Organisation, Coru, etc.;
- Have a promising track record in clinical cancer research exemplified by publications or other relevant research outputs, national/international research partnerships etc.;

  Please note: the Irish Cancer Society assesses the quality and impact of scientific research through means other than journal impact factors alone. The Society recognises the value of all research outputs not only research publications e.g. datasets, patents, community outreach, patient involvement, pre-prints, contributions to consortia etc.
- Currently be resident and hold an appointment in a hospital, healthcare organisation or any research institution in the Republic of Ireland;
- Demonstrate a high level of support from the host institution, training body (where relevant) and peers for the duration of the award;
- Be a member of Cancer Trials Ireland. Please note, any applicants who have not yet received membership can apply here, and successful applicants will only require proof of membership prior to the start date of the funding;
- Be affiliated through their clinical facility with a higher education institution in the Republic of Ireland that is one of the HRB's approved host institutions. The Society will also accept Cancer Trials Ireland as an approved host institution.

Co-Applicants: Each application may include one additional co-applicant. A co-applicant is someone who has a well-defined and substantial role in the development or delivery of the study e.g., significantly contributes to the direction of the research or plays a significant role in the conduct of the research or research-related activity. If proposals are co-designed with key stakeholders (e.g. people affected by cancer), it is important to recognise this by adding them as a co-applicant. A role description and CV is required for the co-applicant.

Official Collaborators: An official collaborator is any individual or organisation that has a significant, distinct, and clearly defined role in the design or delivery of the research and must clearly add value integral to the proposal. Superfluous collaborations or collaborations in name only are not permitted. Up to 5 collaborators can be included per application.

Mentor: Applicants with fewer than 5 years documented clinical trial research experience are required to nominate a mentor. The role of the mentor is to provide guidance and support in terms of the clinical and academic aspects of the research award, such as grant administration, technical requirements, or other healthcare expertise that may be required by the applicant during the duration of the award.

Mentors should be an established senior clinical researcher (>5 years clinical trials research experience), have a history of leading their own clinical trials and studies, a history of grant awards, research supervision, national or international research partnership development, presentation at national or international conferences, etc. The mentor should demonstrate a commitment to ensuring the highest research standard of the proposed body of work.

At a minimum, mentors must meet the following criteria:

- Must hold a post (permanent or on a contract basis), for the entire duration of the research project, at a hospital, healthcare organisation and/ or higher education institution in the Republic of Ireland.
- Possess >5 years' experience in leading out on cancer clinical trial research
- Have a minimum of five senior authorships (first, joint-first, or last) in peer-reviewed academic publications.

A letter of support from the mentor will be required.

2.2. Institution Eligibility

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 based in the Republic of Ireland.

The Irish Cancer Society's policy and preference is for all Host Institutions to be a HRB approved Host Institution as per the list on the HRBs website.

Applicants from non-approved sites (e.g. hospital or health care organisation) or those who are not affiliated with a higher education institution must ideally nominate an approved HRB host institution to manage the grant award funding and reporting.

However, in the case of this award, the Society will also approve Cancer Trials Ireland to be named as an eligible host institution.

2.3. Eligible Research Areas

The Irish Cancer Society are specifically seeking applications for **interventional** clinical studies in the **non-regulated** area including supportive care interventions, radiotherapy studies, surgical trials, survivorship interventions, diagnostics, screening, digital health and technology. Please note: Interventions are defined as a study in which participants are prospectively assigned by the study protocol to receive a specific intervention, or different interventions, to evaluate effects on health outcomes.

Activities supported may include:

- protocol and study design development;
- patient information leaflet and GP letter development';
- patient and public involvement (PPI) activities;
- feasibility and pilot work;
- statistical and methodological support;
- health economics input;
- ethics applications;
- development of recruitment and retention strategies;
- establishment of multicentre collaborations;
- stakeholder and patient engagement activities;

- development of study-specific governance, regulatory, database development and data management plans;
- activities that enhance trial readiness and support future patient accrual.

The Award will not support:

- investigational medicinal product and medical device/ in vitro diagnostic medical devices (IMP/CTIMP/MDR/IVDR) studies;
- basic or translational laboratory research;
- retrospective studies, audits or service evaluations;
- registry-only studies without an interventional component;
- routine clinical care costs not directly related to trial development

For queries on project eligibility, please contact grants@irishcancer.ie

2.4. Patient and Stakeholder Involvement

The Irish Cancer Society is dedicated to putting patients, families, survivors, supporters, and the public at the very heart of what we do. Public and Patient Involvement (PPI) in the research process ensures that research is meaningful and of benefit to those affected by cancer. PPI can be involved at any stage of a research project, from development and design to interpretation and dissemination.

In line with this commitment, it is expected that all applicants include a detailed PPI plan (and the associated minimum allocation of €1,000 to the budget) within their application**. It is strongly recommended that applicants read Appendix 1 'Public and Patient Involvement (PPI) in Research' Guidelines prior to beginning work on an application.**

For the purposes of this award, it is expected that PPI contributors e.g., people who are affected by cancer should play an active role in the development and implementation of the clinical study. As such, we strongly encourage all applicants to partner with PPI contributors as early as possible in the design of their clinical research.

This may include:

- Partnering with PPI contributors to decide on the type of clinical study to be developed.
- PPI contributors being actively involved in the development of the grant application (co-applicants/collaborators).
- PPI contributors providing early input into the design of the clinical study.

- PPI contributors working on the development of patient information material together with clinical professionals and researchers.
- PPI contributors being members of the clinical study steering committee.

It is recommended that applicants make contact with Cancer Trials Ireland as early as possible in the application process to get advice on patient involvement in clinical trials.

2.5. Research Impact

Ensuring that the research funded by the Irish Cancer Society creates an impact has always been a key priority to the Society. In line with our current strategy, the Irish Cancer Society will place a greater focus on maximising and measuring the impact of the research that the Irish Cancer Society funds through our grant schemes. Research impact refers to the potential real-life implications that the research has beyond the lab or academia.

Applicants are required to complete an Impact Plan as part of the application process. The Research Impact Framework (RIF) is a guide on research impact and how to monitor it for those applying for funding from the Irish Cancer Society, and for grant holders who are successful in securing a grant. It is strongly recommended that the RIF is consulted when completing the impact plan and it is included at the end of this document **(Appendix 3)**.

3. Application Procedure

3.1. Application Overview

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

This is a one-stage application process. Once your application has been submitted, an expert international review panel comprised of scientific/clinical reviewers and PPI/PPP reviewers, will evaluate the application submissions. Reviewer feedback will be made available to all applicants on request.

Please note the study design section does not have to be written in accessible plain English; however, it will be reviewed by our PPI panel. Therefore, please consider this when completing this section. We also ask our PPI panel to provide optional comments on the entire application if they wish.

3.2. How to Apply

Applications must be completed and submitted through the Irish Cancer Society's **new** online grant management system. To submit an online application, you are required to register at the following address:
https://irishcancersociety.optimytool.com/en.

When registering, you will receive a verification email from noreply@optimytool.com within five minutes (please check your spam).

Please note: We recommend that you use a non-HSE email address when creating this application to avoid any security issues when receiving correspondence from the Optimy online system.

When you enter your login details, you will be directed to the portal homepage. From here, you can:

1. Update your personal information (please make sure all fields are completed)
2. Change your password
3. Make a new grant application
4. Access previous grant applications
5. Manage any active grants

Once you have created a profile, you will be able to create a new application from the portal homepage. You should select 'Submit a new application' at the top of the homepage, then, then **'**The Clinical Study Seed Award**''**

4. Application Form

There are 10 sections outlined on the left-hand side of the page:

a) Application Outline
b) Lead Applicant Details
c) Study Team
d) Study Design
e) Study Delivery
f) Organisational Support
g) Plain English Summary and PPI Plan
h) Research Impact and Sustainability
i) Budget
j) Validation Summary

Saving your progress regularly is strongly recommended- by clicking 'PREVIOUS SCREEN' you will be brought to the previous section and by clicking 'NEXT' SCREEN you will be brought to the next section, and your application will be saved. Alternatively, you can click 'SAVE AND EXIT'.

Mandatory sections are marked with a red star icon. You will not be able to submit the application if these sections are incomplete.

Further details on each section of the application form:

a) Application Outline

In this section, you will be asked to provide basic information about your application. Input and save the information as required under the following headings:

- Proposed title
- Proposed start date*
- Funding period/grant duration
- Lead applicant details
- Host institution
- Cancer type(s)
- Research type(s)
- Keywords
- Non-regulated interventional category:

***Please Note**: The earliest date we can process a contract for this grant is December 2026 therefore the proposed start date must be within the 2027 calendar year.

b) Lead Applicant details

In this section you will be asked to provide greater detail on the suitability of the applicant, including CV.

Clinical research experience: Please describe your experience in an oncology-related discipline and in clinical cancer research **(300 words max).**

Applicants CV: Please upload your CV - completed using the template provided (the template is downloadable in this section on the online system or on the website). More information on each section is given in the template.

Please only fill in relevant details, certain sections can be left blank if not applicable to the applicant's career stage. You will not be penalised for this. Senior applicants would be considered those who have more than 5 years of experience leading clinical trials.

To upload your CV, either drag files into the upload box to attach or click 'BROWSE FILES', choose your file, then click 'Open'. This must be in pdf format, using the Irish Cancer Society Senior (>5 years clinical trial experience) or Junior CV template.

c) Study Team

Co-applicant:

One additional co-applicant may be listed on each application.

Role in clinical study: Please provide details of the co-applicant and explain their role in the proposed study (150 words max.).

Co-applicants CV: Please upload your co-applicants CV - completed using the template provided (the template is downloadable in this section on the online system or on the website). More information on each section is given in the template.

Please only fill in relevant details, certain sections can be left blank if not applicable to the co-applicant. You will not be penalised for this. Senior applicants would be considered those who have more than 5 years of experience leading clinical trials.

To upload the CV, either drag the file into the upload box to attach or click 'BROWSE FILES', choose your file, then click 'Open'. This must be in pdf format, using the Irish Cancer Society Senior (>5 years clinical trial experience) or Junior CV template.

Collaborators:

Please indicate if you plan to include collaborators within your project. If there are collaborators, please explain their roles and their suitability for the proposed research. In this section, you should provide information on the knowledge, experience, and expertise of the team and how this team will enable you to deliver the study (**500 words max.**).

Mentorship

Please nominate a mentor if you have < 5 years clinical trial experience.

Mentor Role Description: Please detail why you have chosen your mentor and how they will support you during the clinical study that you are proposing **(300 words max.).**

Mentors CV: In this section you are required to upload the CV of your mentor. Please upload your mentors CV - completed using the template provided (the template is downloadable in this section on the online system or on the website). More information on each section is given in the template.

Please only fill in relevant details, certain sections can be left blank if not applicable to the mentor. You will not be penalised for this.

To upload the CV, either drag the file into the upload box to attach or click 'BROWSE FILES', choose your file, then click 'Open'. This must be in pdf format, using the Irish Cancer Society Senior (>5 years clinical trial experience) template.

Mentors Letter of Support: In this section you are required to upload the letter of support of your mentor. Please upload your mentors Letter of Support using the - template provided (the template is downloadable in this section on the online system or on the website).

To upload the letter, either drag the file into the upload box to attach or click 'BROWSE FILES', choose your file, then click 'Open'. This must be in pdf format.

d) Study Design

In this section you should include as much information as possible on the design of the non-regulated intervention.

Intervention Details	Please provide details of the intervention you propose to examine and **how it fits within the remit of a non-regulated** study **(300 words max.).**
Background and Scientific Rationale	Please detail any background or supporting information that underpins your proposed clinical study. For example, you may wish to include details on the scientific rationale of the study and study design or data and results from previous pre-clinical and clinical studies. (**500 words max.**).
Aims	Please outline the overall aims of the proposed clinical study, and how this study will benefit the lives of cancer patients (**300 words max.)**.
Ethical Considerations	Please outline any relevant ethical considerations, applications to review committees or ethical approval in place for the proposed study **(300 words max.).** You may wish to include any relevant documentation.

Study Design Uploads: you may optionally upload up to three relevant and accessible research images.

To upload the files, either drag the files into the upload box to attach or click 'BROWSE FILES', choose your file, then click 'Open'. This must be in pdf format

e) Study Delivery

Research Plan	Please provide details of the proposed study design and methodology, including the study population, eligibility criteria, primary and secondary endpoints, recruitment strategy, and study procedures. If this is a multi-site study, please list all proposed study sites and the recruitment target

	at each site. Briefly describe the proposed statistical analysis and justify the planned sample size **(750 words max.).** Please attach schematic of the proposed study. To upload the files, either drag the files into the upload box to attach or click 'BROWSE FILES', choose your file, then click 'Open'. This must be in pdf format.
Data Management	Describe your approach to data management and stewardship during and after the study. Please outline the types of data that will be collected or generated, how data will be stored, protected and managed, any plans for data sharing or retention, and who will be responsible for data management activities **(250 words max.)**.
Project Management and Oversight	Describe how the project will be managed and overseen. Include key roles and responsibilities, project monitoring arrangements, risk management processes, and any oversight mechanisms that will be used to ensure delivery of the study in accordance with the protocol **(250 words max.).**
Estimated Timeline	Please attach details of an estimated timeline for the study using a Gantt chart (or other visual aid) and include any necessary ethical considerations. To upload the files, either drag the files into the upload box to attach or click 'BROWSE FILES', choose your file, then click 'Open'. This must be in pdf format. Please note, it is expected that patient accrual on this study will commence over the lifetime of the award.

f) Organisational Support and Practicalities

It is critically important that the applicant has support from both the:

- Host institution
- Lead applicants employing hospital or clinical practice setting

The Host Institution will be responsible for administering the award and managing all associated contractual, financial, and reporting obligations. The Host Institution must be aware of the application and confirm its capacity to fulfil all requirements associated with the award, including contract negotiation, financial management, governance, and reporting.

Applicants must also demonstrate support from their employing hospital or clinical practice. Given the demands on clinical services and workforce capacity, it is important that any clinical organisation involved in the application is aware of the proposed study and supports the applicant's participation. Applications should provide evidence that the broader clinical team and institutional environment will facilitate successful project delivery, including any protected time, infrastructure, personnel, or other local resources that will contribute to the project.

Failure to follow through in a timely manner on the commitments made i.e., in the acceptance, processing or discharge of this award, may result in invalidation of this award offer, and lead to it being awarded to the secondary candidate.

Organisational Support Question: Please detail the steps, both in the host institution and in the clinical setting, that will need to be taken to ensure organisational sign-off for this award should you be successful.

If you have academic/teaching/other commitments these must also be considered. **(300 words max.).**

Organisational Letters of Support: An unequivocal and strong letter of support is required from each:

- the host institution
- the hospital/clinical setting

The letters of support must make clear that each organisation is aware of the application and fully commit to supporting processing the award should the applicant be successful

It must also be clear in both letters of support that the host institution and the hospital/clinical practice have communicated on the application and agree to support the application.

The ‘Letter of Support’ template must be used (can be downloaded in this section of the online application).

To upload the letters, either drag the files into the upload box to attach or click ‘BROWSE FILES’, choose your file, then click ‘Open’. This must be in pdf format.

Organisational Practicalities: Please detail the practicalities involved in how you will undertake and deliver on the research plans outlined. For example, will you yourself be undertaking the research full time or part-time? If part-time, how will you balance your research commitments with your clinical commitments? Etc. The plan should include details on protected time logistics if relevant i.e., who will cover your clinical activities if you are applying for protected time and what days of the week you plan to use the protected time etc. (300 words max.).

g) Plain English Summary & PPI Plan

PPI should be built into the application from the very beginning.

In this section, please provide an accessible summary of the proposed study and your plan for co-developing and integrating clearly identifiable patient involvement. An expert PPI Panel will review this section. As such, please use plain accessible language and if technical terms are used, they must be explained. Patient involvement and partnership is a fundamental aspect of the application. Please consult **Appendix 1** before completing these sections.

Plain English Summary: Please provide a detailed and structured plain English summary detailing the following **(300 words max.)**:

- A brief outline of the background of your research proposal i.e. how and why your proposal came about and the context in which your proposal will take place;
- A description of the specific problem, issue, or question that you are asking in your research proposal and describe how you are addressing it (including the variables being measured and why you have chosen these specific variables);
- An outline who will *participate* in your, how you intend to recruit them into your study, and what they will be expected to do if they take part;
- Details on the relevance and importance of the proposed research for people affected by cancer.

PPI Involvement Plan: The involvement plan should detail how people affected by cancer and any other relevant stakeholder will be *involved* in the study as partners. It should be well thought out, as detailed as possible, and given as much consideration as the scientific sections in the form. Vague plans are to be avoided. When completing this section, please detail the following (**500 words max.**):

- What is the overall goal of your PPI plan?

- What are the aims and objectives of your PPI plan?
- At what stage of the research programme will patients and other stakeholders be involved (PPI partners) e.g. planning, design, implementation, management, evaluation, dissemination?
- What will be expected of the patients and stakeholders who become involved? What is the burden of involvement and how will people's time and expenses be compensated?
- Please describe any patient or stakeholder involvement that has occurred to date in the development of the proposal.
- How will the planned involvement activities influence the research and how will you ensure that the involvement activities are not tokenistic?
- What key patients and stakeholders will be involved, how many will be recruited, and from where will they be identified?
- How much time do you estimate will be required of the PPI partners and what is the timeframe involved?
- What are the practicalities and logistics of the PPI partnership? How will you communicate? Where will you meet?
- Articulate the challenges that might arise from involving PPI partners in your research and how any issues will be prevented or overcome.
- How will you support PPI partners to be involved in your study?
- Have you considered any accessibility issues the PPI partners might have?
- How will you ensure that results and outputs emerging from the study are fed back to regularly the PPI partners?
- What PPI supports are available to you locally or nationally to advise you on your PPI and how will these supports be utilised?

Please note, if your host institution is part of the PPI Ignite Network, it is strongly recommended that you contact your host institution lead site, for support on submitting this application. More details can be found here. It is also recommended that applicants make contact with Cancer Trials Ireland to get advice on patient involvement in clinical trials.

While patient participation and engagement activities are encouraged as part of an application and can be detailed as part of this plan, the Society will only fund applications that predominately include involvement or partnership activities. Please see Appendix 1 for further details and examples.

Sharing of Research Findings: As the largest voluntary funder of cancer research in Ireland, the Irish Cancer Society relies on the generous donations from the public in order to fund cancer research. A key priority is, therefore, 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, in particular 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, social media content, etc. (**200 words max.**).

It is strongly recommended that applicants read Appendix 1 'Public and Patient Involvement (PPI) in Research' guidelines prior to beginning work on this section.

Please note, The PPI Review Panel will review this section. It should be written in a manner that is accessible to a non-scientific audience.

h) Research Impact

Ensuring that the research funded by the Irish Cancer Society creates an impact has always been a key priority to the Society.

In line with our strategy 2020-2025, from 2021 and beyond, the Irish Cancer Society will place a greater focus on maximising and measuring the impact of the research that the Irish Cancer Society funds through our grant schemes. Research impact refers to the potential real-life implications that the research has beyond the lab or academia.

Going forward, applicants will now be required to complete an impact plan as part of the application process.

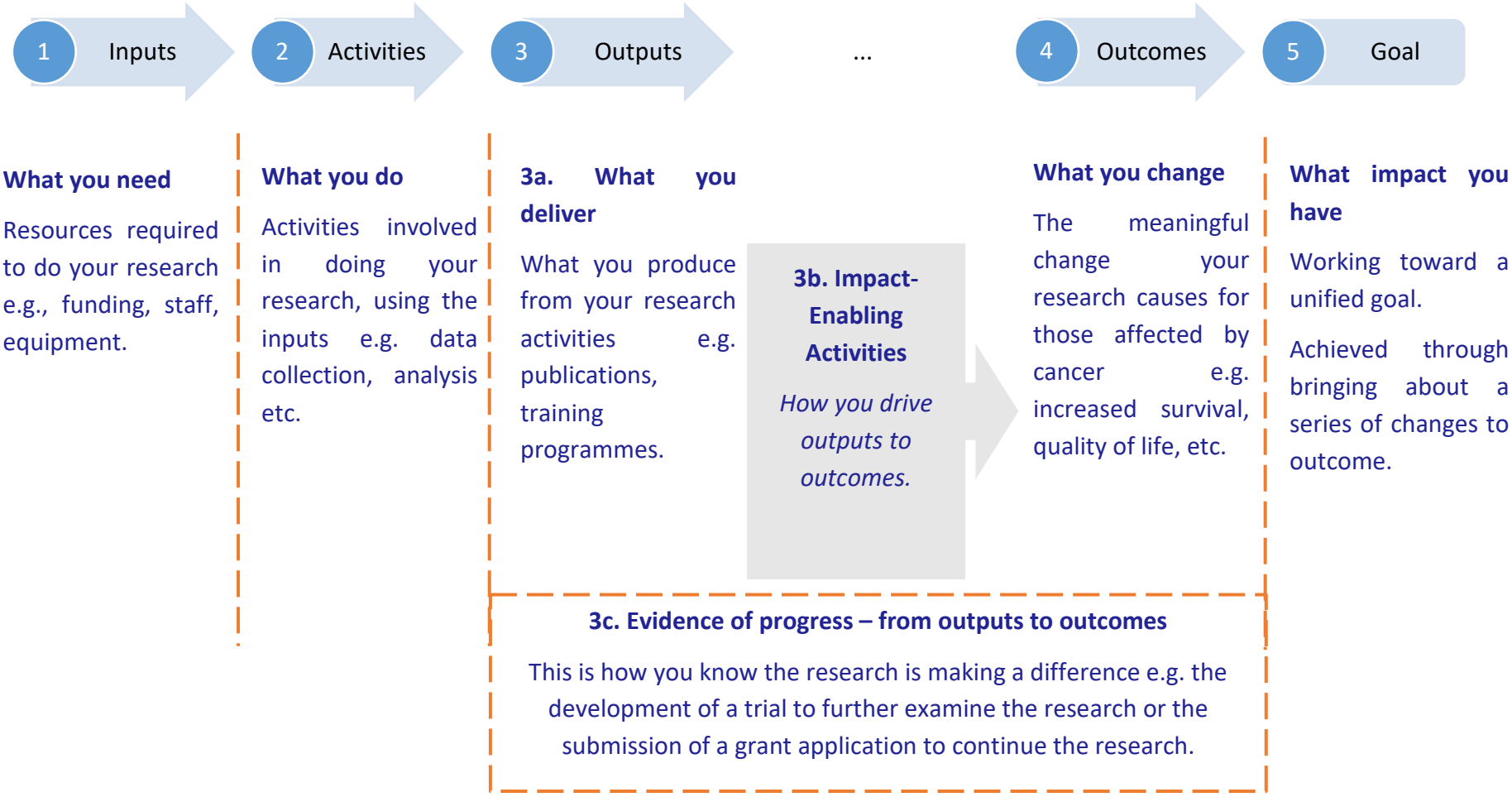
The Research Impact Framework (RIF) is a guide on research impact and how to monitor it for those applying for funding from the Irish Cancer Society, and for grant holders who are successful in securing a grant. It is strongly recommended that the RIF is consulted when completing the impact plan and it is included at the end of this document (Appendix 3).

Impact Plan: Please consult the Research Impact Framework (RIF) (Appendix 3) when completing this section.

Creating impact from the research that we fund has always been of great importance to the Irish Cancer Society. The purpose of including an impact plan at the application stage is to focus all projects on working towards achieving impact from the outset in line with the Irish Cancer Society's strategic objectives 2020-2025.

The impact plan details how the input of research funding ultimately results in meaningful impact for people who are affected by cancer. Therefore, it is the impact of the research beyond academia, i.e., the real-life benefit of the research and how this may improve the lives of people who are affected by cancer.

An impact plan can be designed using a sequence of steps, as follows:



It is important to start thinking about the pathway to impact from the start of the project. We are aware that the impact plan provided by researchers at the application stage may be somewhat limited as the project has not yet started, it can be difficult to predict research results, and how a research landscape may change over time. When applying for a grant or planning a research project, you usually have a goal or question that you aim to answer by completing the project. However, it is the Society's duty to ensure that the research we fund makes a difference to the lives of those who are affected by cancer. Therefore, all research funded by the Irish Cancer Society should aim to have an impact on the lives of those who are affected by cancer and make steps towards a positive change. It is important that you are realistic; there is no need to overstate the impact of your research. Impact can be direct and indirect, and it may happen slowly over time. The Irish Cancer Society is aware of this and understands every project in different.

For the Irish Cancer Society, research impact is defined as:

'Research being used to bring about a positive change to the lives of people affected by cancer'.

Therefore, thinking about the tangible impact of your research will provide you with a strong foundation when a grant gets underway. As such, plans should be as comprehensive and considered as possible. The recommended approach is to develop the impact plan by working backwards, from goal to inputs.

As such, the impact plan consists of:

5. Goal

4. Outcomes

3*a*. Outputs

3*b*. Impact-enabling activities

3*c*. Evidence of progress

2. Activities

1. Inputs

Please note: Both the PPI and Scientific Review Panels will review this section. **It should be written in a manner that is accessible to both reviewer groups.** Further details on each section follows:

Section	Description & Information given to applicant	Worked Example
5. Goal	This is the goal of the Irish Cancer Society. It is pre-determined by the Strategy 2020-2025 and cannot be changed. This goal is that 'by 2025, 3 out of 4 Irish cancer patients will survive their diagnosis and everyone affected by the disease will have access to world-class treatment, care and support. In future, no one in Ireland will die from cancer.' This is the goal that all research funded by the Irish Cancer Society should be working towards. Please note, you will not be required to add anything additional to this category of the impact section.	This is fixed to the Irish Cancer Society set goal so will always be the same: By 2025, 3 out of 4 Irish cancer patients will survive their diagnosis and everyone affected by the disease will have access to world-class treatment, care and support. In future, no one in Ireland will die from cancer
4. Outcome	To reach the above goal, a number of core changes or 'outcomes' must first be accomplished. These outcomes, identified through stakeholder consultation, will drive us toward our goal. You must select at least one outcome from the below list: — Treatments and diagnostics increase survival. — Treatments and diagnostics increase the quality of life of people affected by cancer. — Increased numbers of patients accessing clinical trials and early access programmes. — Screening increases survival. — Improved care and support increase survival.	This trial involves examining a new treatment for bowel cancer. Therefore, the first Irish Cancer Society outcome would be the most appropriate to use here: Outcome 1: Treatments and diagnostics increase survival. Outcome 2: Treatments and diagnostics increase the quality of life of people affected by cancer. Outcome 3: Increased numbers of patients accessing clinical trials and early access programmes

	— Improved care and support increase the quality of life of people affected by cancer. — People affected by cancer feel more empowered in their cancer journey. You may choose 'other' if you feel strongly that none of the other outcomes covers the potential outcome of your research. If 'other' is selected, then more detail will be required on the proposed outcome. By targeting a strategic outcome, every funded study funded is contributing to the Society's goal.	
3a. Outputs	Planned outputs for the project e.g. publications, newsletters, a website policy document, patents, information leaflets, reports, and training programmes etc. (150 words max). These are just examples and are not a comprehensive list. The appropriate outputs will vary for each type of project and what outcome has been selected.	The publication of a paper on the outcome of the study.
b. Impact-enabling activities	An output is unlikely to achieve a desired outcome on its own. Impact-enabling activities bridge the gap between **outputs** and **outcomes.** Please detail what activities need to occur for the outputs to impact the identified outcome. When will these activities take place? Information can be provided in narrative or bullet point format (300 words max).	Using the above output as an example, the impact enabling activity could be a workshop with key stakeholders (scientists, clinicians, people affected by cancer) in the field to discuss the findings from the publication and make a plan on how best to build more scientific evidence or bring the evidence into the clinic.

c. Evidence of progress	Please detail how you will measure the effectiveness of impact-enabling activities i.e. how do you know your activity made a difference? What evidence can be used to show this? Indicators may be qualitative (descriptive or non-numerical) or quantitative (numerical) (300 words max).	Using the example provided in 3.b, the evidence of progress could be the development of a grant application in collaboration with key stakeholders to complete another more extensive clinical study (this would be an example of qualitative evidence). It could also be details on how additional funding was obtained to develop the research further (this would be an example of qualitative evidence).
2. Activities	Please outline the activities that will take place as part of the research project. As a lot of this has been provided in detail as part of the methodology section of your application, a high-level summary of what will be done over the course of the funding period is sufficient. Bullet points may be used (150 words max).	Accrual of patients on to the study.
1. Inputs	Please detail the resources needed for the project. As a lot of this has been provided in detail as part of your application, a high-level summary is sufficient. Bullet points may be used (150 words max).	• Funding to pay for the research project to be undertaken. • Protected time for the lead clinician.

i) Budget

Funding may be requested for costs directly related to the development, activation and early delivery of a non-regulated interventional cancer clinical study. Eligible costs include research personnel support (e.g. research nurses, trial coordinators, data managers and statisticians), protocol and study development activities, research governance, feasibility and pilot work, patient and public involvement (PPI) activities, ethics and data protection activities, data management and database development, health economics and statistical and methodological support, recruitment and patient accrual initiatives, site engagement and study start-up activities, dissemination costs and training opportunities that support the development of the Clinical Principal Investigator and the successful delivery of the proposed study.

All costs must be clearly justified and demonstrate how they will contribute to trial readiness, patient recruitment, study delivery, or the future sustainability and competitiveness of the research programme.

Given the high cost often involved with developing and running clinical trials, it is anticipated and acknowledged that the overall costs associated with the clinical study outlined as part of this application may be much larger than the €100,000 injection of funding provided through this seed award. Therefore, we ask in this section to include a budget and budget justification detailing only the specific costs associated with the Irish Cancer Society contribution of €100K funding.

Indirect costs/overheads are not eligible costs for Irish Cancer Society awards

Ineligible Costs

Funding may not be used for costs unrelated to the development or implementation of the proposed non-regulated interventional study. Ineligible costs include costs for investigational medicinal product (IMP/CTIMP) studies, basic laboratory or pre-clinical research, retrospective studies, audits and service evaluations, routine clinical care costs that would have been incurred irrespective of the research, institutional overheads, capital equipment, tuition fees, conference attendance not directly related to the study, publication costs, and activities that have already been completed prior to the award start date, costs already supported or claimed through another funding source, and costs not directly attributable to the proposed study.

The award is not intended to support the full conduct of large-scale definitive trials or costs that cannot be clearly justified as contributing to study development, implementation, patient accrual, investigator development or sharing of research findings.

Approval of all budget items is at the discretion of the Irish Cancer Society. Any budgeted costs that do not adhere to spending guidelines risk rejection.

Direct costs that can be requested for the following budget categories:

Budget Item	Details
Personnel costs	The Irish Cancer Society will allow researchers to utilise a proportion of the budget to fund their or another staff members protected time to carry out the research activities. These costs towards research time should be calculated using the most up-to-date HSE or IUA salary scales, as appropriate, and include employer PRSI and pension contributions. Applicable annual increments (e.g. 2.5%) per annum should be included. A breakdown of each cost is required, detailing and justifying a) the point, level, and scale used, b) the employer PRSI contribution, c) the employer pension contribution, d) any annual increments, and e) the FTE (full time equivalent) of each post. Scales: HSE: https://www.hse.ie/eng/staff/benefitsservices/pay/ IUA: https://www.iua.ie/research-innovation/researcher-salary-scales/
Trial development and implementation costs	Funding may be requested for reasonable and appropriately justified costs associated with the development, activation and implementation of a non-regulated interventional clinical study. This may include site set-up and study start-up costs, patient recruitment and enrolment activities, research and trial management personnel, data and quality management, statistical support, or any other costs necessary to support successful trial delivery and patient accrual.
Equipment	The Irish Cancer Society will allow researchers to purchase small equipment items up to a maximum value of €3,000. A strong justification must be provided for each equipment item, and a rationale must be given as to why this item is not already available to the researcher at their host institution. Only equipment items that are specific to the research project will be allowed. All costs must be inclusive of VAT, where applicable. Requests for large pieces of equipment will not be funded. The purchase of computer equipment will be considered for any grant of over 24 months' duration, provided a strong rationale is given at the time of grant application. The

	maximum allowed budget for the purchase of a computer or laptop is €1,500.
Training costs	Education and training for members of the team may be budgeted provided they are relevant to the specific study being proposed. This may include attending courses, workshops, professional development training, etc. Include any training-related travel and accommodation costs here.
PPI costs	Costs associated with involvement activities should be budgeted (a minimum of €1,000 should be budgeted for involvement activities). This is specifically in relation to any costs associated with involving PPI contributors as partners on your clinical study. Research participant costs i.e., costs associated with patients participating in your clinical trial or study must be budgeted as part of the study running costs not part of the PPI costs. Please see Public and Patient Involvement (PPI) in Research Guidelines when developing a PPI budget (Appendix 1).

Completion of Budget Tables: Please specify for how many years you are allocating budget. Please note this Award will cover up to 5 years of funding. Once number of years are specified, please complete all relevant budget tables.

Budget Justification: It is very important that the costs associated with each category of budget are justified in full. Please include calculations of costs were relevant. Failure to justify each category listed in the budget table will result in an ineligible application.

Plan for additional research costs: you will be required to specify if the overall costs associated with the proposed study are higher than €100,000 i.e. if more funding is required outside of the Irish Cancer Society's allocation.

Please outline the following in relation to the need for additional sources of funding:

- The overall cost of the clinical study that you are proposing
- Details of confirmed and anticipated sources of any additional funding **(200 words max.).**
- An explanation of how the study will proceed if further funding is not secured **(200 words max.)**.

j) Validation Summary

The validation summary page will notify you of any incomplete sections. You will not be able to submit the application until all required sections are complete.

5. Submission of the Application

The application is ready for submission once the form has been validated on the validation summary page. Once the application has been validated, it may be submitted by the lead applicant. Once the application has been validated, it may be submitted by the lead applicant by clicking 'VALIDATE AND SEND'.

Applications must be received by the Society prior to the deadline. Late or incomplete applications will not be accepted.

Application Checklist:

- ✓ Completed application form
- ✓ Applicant CV
- ✓ Study Team CVs
- ✓ Letters of Support (Mentor (if applicable), Host Institution, Hospital site/ clinical practice)
- ✓ Supporting documentation (if applicable)
- ✓ Study Schematic
- ✓ Gantt Chart

6. Application Assessment

The Irish Cancer Society bases its funding decisions on the recommendations of an external review panel (scientific and PPI). However, the Society withholds the right to reject any funding application at its own discretion.

Incomplete, ineligible, or late applications will be rejected by the Society and may not proceed to external review.

6.1. Conflicts of Interest

The Society endeavours to ensure that external reviewers are free of any conflicts of interest that might unduly bias the decision-making process.

6.2. Assessment Procedure

Applications are reviewed by a panel of international clinical experts (scientific panel) **AND** a panel of experts by experience (PPI panel). The scientific panel will consist of experts in the areas of clinical research. The PPI panel will be made up of individuals with a lived experience of cancer. Sections of the application will be assessed in the following way:

	PPI Panel	Scientific Panel
Full Application	• Application Outline • Lead Applicant Details • Study design • Plain English Summary & PPI Plan • Research Impact • PPI Budget • Optional comments on the overall application	• Application Outline • Lead Applicant details • Study team • Study design • Study delivery • Organisational Support • Overall Budget

It is vital that the sections reviewed by the PPI panel are written in **plain accessible English***. Failure to do this may result in the PPI representatives being unable to accurately score and provide feedback on these sections of your application. The review panel will be asked to provide feedback on the budget, which the Society will take into consideration. The approval of all grant budget items is at the discretion of the Irish Cancer Society.

*Study design does not have to be written in plain accessible English.

The review panel will select awardees based on the applicant(s) who make the most compelling argument that their proposed study will actively drive patient accrual in Ireland within the lifetime of the award and for the application that is most likely to benefit the lives of those who are affected by cancer.

The review panels will assess your proposal based on:

- The clinical and scientific importance of the research question;
- The alignment of the proposed research with the Irish Cancer Society strategic priorities, namely clinical trials;
- The potential impact of the study on the lives of those who are affected by cancer;
- The strength of the study design including scientific rationale;
- The strength of the applicant and study team;
- The feasibility of the proposed clinical study;
- Likelihood of patient accrual to the study;
- Appropriate and considered public and patient involvement;
- Strength of the plan to communicate the findings of the study to all audiences;

6.3. Assessment Outcome

Reviewer scores will be compiled and evaluated during a review panel shortlisting meeting. Applicants will be informed about the outcome of the review by email. Shortlisted applicants will be invited for an interview.

7. Contact

If you require assistance with the online grant management system or have any questions about the grant call, please contact the Irish Cancer Society Research Department:

Email: grants@irishcancer.ie