All Ireland NCI Cancer Consortium (AICC)

Research & Innovation Grant Scheme 2024

Full Application Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	04 June 2024
Application Closing Date	26 July 2024 @13:00

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie), and this system will close automatically at the stated deadline and timeline listed above.

**Prior to final submission to the HRB, all applications must first be reviewed and approved within GEMS by the authorized approver at the Host Institution as listed in the application form. It is critical therefore that applicants leave sufficient time in the process for the Research Office (or equivalent) in their nominated Host Institution to review, seek clarifications and approve applications prior to the final submission date. This may involve being aware of and complying with any internal Host Institution deadlines for review and approval, distinct from the HRB deadline.*

Table of Contents

Introduction

The Health Research Board's (HRB) Strategy[1] sets out our leading role to invest in research that delivers value for health, the health system, society, and the economy. The HRB achieves this by engaging with partners in the health and social care system and with other funders to facilitate dialogue on key issues and agendas to ensure stronger collaboration, coordination, and prioritisation. The HRB collaborates with the Health & Social Care (HSC) Public Health Agency and other stakeholders in Northern Ireland to advance all island activities in areas of mutual interest.

The HSC, established in 2009, is responsible for the administration and coordination of the research & development budget on behalf of Department of Health, Northern Ireland (DoH NI). Through its current strategy, Research for Better Health and Social Care Strategy (2016-25)[2], it seeks to ensure that research and development is an integral part of ensuring that health and social care services are of the highest quality and informed by the best available and up-to-date evidence.

The Ireland-Northern Ireland-National Cancer Institute Cancer Consortium (AICC) was originally launched in October of 1999, with the aim of reducing cancer incidence and mortality on the island of Ireland through cross-border and transatlantic collaborations in cancer research and education.

Cancer services across the island had undergone major restructuring because of several government reports. Specifically, the National Strategy Document for Cancer proposed that cancer treatment services should be centred around primary care services, regional services, and a national coordinating structure. Therefore, this was an opportune time to bring the National Cancer Institute (NCI) on board in a determined effort to redevelop and significantly improve services and outcomes for cancer patients throughout the island. The Consortium was regarded as a major step toward enhancing diplomatic relations between the United States, Ireland, and Northern Ireland, bringing the governments of the United States and both parts of the island together in the fight against cancer.

In March 2021 a new MoU was signed by Minister for Health Stephen Donnelly TD, Northern Ireland Minister for Health Robin Swann MLA, and Dr Norman E Sharpless MD on behalf of the NCI during a special virtual broadcast ahead of Saint Patrick's Day celebrations.

The MoU serves as an enabling framework, supporting cancer care and cancer research priorities, and offering more opportunities to develop North-South and Ireland-US collaborations. The renewed Consortium builds on previous successes and will provide an excellent framework to support national coordination of cancer research, which is one of the key research actions in the National Cancer Strategy 2017-2025.

Priority themes for the All-Ireland NCI Cancer Consortium include prevention and integrated care pathways, research capacity, clinical trials, genomics, and precision medicine.

Since 2021, the HRB has worked with the Department of Health (DoH) to establish an implementation mechanism and put in place appropriate structures to oversee the Consortium to ensure ongoing commitment to, and longevity of, the initiative.

[1] https://www.hrb.ie/strategy-2025/

[2] https://www.health-ni.gov.uk/publications/research-better-health-and-social-care-strategy-2016-25

The current structures include:

- A Steering group made up of representatives of the three signatory parties.
- An Implementation group, currently chaired by the CEO of the HRB, Dr.Mairead O'Driscoll, and Prof.Cherith Semple from the University of Ulster, with representatives from health agencies (National Cancer Control Programme and equivalent in NI, National Cancer Registries (North and South), HRB, NCI, HSC Public Health Agency (NI) and from the research community (Cancer Trials Ireland, AICRI).
- Working groups (WG) in the three priority areas with membership drawn mainly from the above Implementation group:
    - Cancer Care Delivery and Survivorship
    - Clinical Research and Trials
    - Genomic and Precision Medicine

Both the HRB and HSC R&D Division have long supported the Cancer Consortium in a wide spectrum of its research-related activities and will now launch the AICC Scheme.

This is a dedicated funding stream to support research proposals within the three key priority areas identified by the AICC. It is a timely investment for the AICC's 25th Anniversary in September 2024.

Aims & Objectives

The aim of the AICC scheme is to support innovative, dynamic, and collaborative cancer research and innovation within the three key priority areas identified by the AICC to benefit all-island cancer patients.

The objectives of this scheme are:

- To stimulate, engage, develop, and improve all-island and trans-Atlantic multi-disciplinary cancer research collaborations, networking, and engagement.
- Prime cancer research activity within the three key AICC priority areas:
    1. **Cancer Care Delivery and Survivorship**
    2. **Clinical Research and Trials**
    3. **Genomic and Precision Medicine**
- Support high quality, innovative cancer research pilots, mapping activities, projects and/or training initiatives.

The overall goal of the consortium awards is to increase the level of collaboration and innovation amongst cancer researchers and experts across the three jurisdictions of Ireland, Northern Ireland, and the United States.

As such we expect collaboration across the three jurisdictions to form a key component of the research proposal. All applicants will be required to have cross border collaborators as co-applicants to be deemed eligible to apply e.g., a Lead Applicant from the Republic of Ireland requires a Co-Applicant from Northern Ireland and vice versa. Additionally, applicants will be required to have an NCI researcher/research group as a collaborator, or other as appropriate. However, research proposals which are solely focused on strengthening and, or improving North-South cancer research

and innovation collaborations may apply with sufficient justification for exclusion of NCI partners in the proposal. These are expected to be in strictly limited circumstances.

Applications can be submitted for pilot projects, mapping activities, standalone research projects, or the establishment of a training scheme/programme, or similar.

Scope of Call

The AICC scheme is intended as a dedicated pilot-& learn funding stream to enhance, extend, and strengthen research and innovation capability, across the island of Ireland supported via trans-Atlantic partnerships.

Proposals must align with the HRB Strategy 2021-2025 and National Cancer Strategy for either one or both jurisdictions (North/South).

Collaborative scientific research projects including mapping, networking, and pilot activities and/or exchanges and training of researchers and experts will be supported.

The research proposal must fall under one of three priority themes as identified by the AICC:

1. **Cancer Care Delivery and Survivorship**
2. **Clinical Research and Trials**
3. **Genomic and Precision Medicine**

The AICC award is intended as a strategic and focused investment and must demonstrate added-value above and beyond any research activities, collaboration or networking that is currently taking place.

Where an application does not address the aims, objectives, and scope of the call, the application will be deemed ineligible and will not be accepted for review.

Out of Scope

Where an application is outside the scope of the scheme, the application will be deemed ineligible and will not be accepted for review.

Out of scope for this scheme:

- Applications which are solely or predominately developing the infrastructure for biobanking, databases or patient registers*.
- Applications which are solely or predominately health service developments without a predominant research element. The HRB will not fund the cost of providing the service itself, only the research element.

- Applications from individuals applying for, holding, or employed under a research grant from the alcohols industry, tobacco industry or related actors.[3,4]
- Infrastructure involving building work, fit-out of buildings, or purchase of major pieces of equipment.
- Applications involving basic biomedical research.
- Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
- Applications using cell lines, animals or their tissue that do not constitute pre-clinical research (see Appendix II for a definition of pre-clinical research in the context of this scheme).
- Applications which are solely literature reviews, audits, questionnaires/surveys, or technology development (although these elements may be part of an integrated mapping activity, pilot or project/research study).
- Applied research projects to generate evidence for local/national health and social care needs/priorities, where the results are not generalisable or actionable beyond the local/national setting. Such applications may be suitable for submission to the HRB Applied Partnership Awards (APA) scheme.
- Applications seeking to evaluate a definitive intervention or a stand-alone feasibility study[5] for a definitive intervention. Such studies are supported through the HRB Definitive Intervention and Feasibility Awards (DIFA) scheme.

**Due to the critical importance of having a sustainable funding model and appropriate governance for patient registries, this scheme should not be used to establish new registries or to subvert the costs of maintenance of existing registries. Consideration can be given, however, to expanding and optimising the use of registries to support cancer research.*

Funding Available, Duration and Start Date

The AICC Scheme design is a two-tiered scheme intended to maximise and stimulate potential activity and impact within the three key priority research areas identified by the AICC.

- ***Tier one*** of the scheme is designed to allow for smaller scale applications which involve pilot projects or mapping activities due to occur over a maximum duration of two years to apply for funding, exclusive of overheads, up to a maximum of €100,000.

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[3] *Any company, entity, or organisation involved in the development, production, promotion, marketing, or sale of tobacco in any country of the world. The term also includes any companies that are a subsidiary or a holding company or affiliate of the above. This also includes e-cigarette companies and non-tobacco related companies which are fully or partially owned by the tobacco industry.*

[4] *Including social aspects/public relations organisations (SAPROs) funded by alcohol companies or trade associations in which such companies are members.*

[5] *Sandra M. Eldridge et al. Defining Feasibility and Pilot studies in preparation for Randomised Controlled Trials: Development of a conceptual Framework. PLoS ONE 11(3): e0150205*

Mapping activities may include cross-border needs assessments e.g. in relation to education/training or cancer research needs to improve cross-border cancer collaboration and activity. Audits/surveys or questionnaires alone are not eligible unless part of a larger mapping activity project.

- ***Tier two*** is for specific, targeted projects or potential training initiatives which may occur over a maximum 3-year duration to apply for funding awards, exclusive of overheads, up to a maximum of €330,000.

The total funding envelope for the AICC scheme including overhead contribution is €1,200,000. The awards allocated across tiers will be decided by international panel review and scoring.

The AICC 2024 award will provide support for research-related costs including salary for research staff, running costs, FAIR data management costs, equipment and dissemination costs, and overheads contributions. The HRB will calculate overheads during contracting.

Note: The AICC 2024 Award will not fund the salary and related costs of tenured academic staff within research institutions (including buy-out from teaching time etc.).

The budget requested and the award duration must reflect the scale and nature of the proposed research with sufficient justification. Reviewers will thoroughly assess each application, the level of funds and timeframe requested.

Eligible scheme costs include:

- Contributions to personnel costs: for example, AICC Project Research Coordinator (to ensure coordination across Ireland and connectivity with external collaborators).
- Running costs: for example, travel costs, PPI costs, training and exchange bursaries, networking events
- Dissemination and knowledge exchange costs
- Overhead contribution of 25-30% based on the proposed activity.

The earliest start date of the Grant is 01 November 2024.

Eligibility Criteria

This call is open to HRB recognised Host Institutions from the Republic of Ireland and Northern Ireland.

Applicant Team

Applications should be made on behalf of a team made up of researchers, knowledge user(s) and PPI contributors.

All applicants will be required to have cross border collaborators as co-applicants to be deemed eligible to apply e.g., a Lead Applicant from the Republic of Ireland requires a co-applicant from Northern Ireland and vice versa. Additionally, applicants will be required to have an NCI collaborator, however research proposals which are solely focused on strengthening and, or improving North-

South cancer research and innovation collaborations may apply with sufficient justification of NCI exclusion. Exclusion of NCI is expected to be in specific limited circumstances.

The Lead Applicant will serve as the primary point of contact for the HRB during the review process and on the award, if successful. The Lead Applicant will be responsible for the scientific and technical direction of the research project. They have primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of the HRB.

The Lead Applicant **must**:

- Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the island of Ireland (the "Host Institution") as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable.

  OR

- Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

They **must** show evidence of achievement as an independent researcher in their chosen research field by:

a) Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs (e.g., published book chapters, reports to government, research data and datasets, research materials, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence on health policy and practice, outreach and/or knowledge translation activities, media coverage or other relevant activities) and/or any other relevant outputs that have resulted in a significant impact in their field.

b) Demonstrating record of independence by showing that they have secured at least one peer-reviewed research grant for a research project/s, as either the Lead Applicant or a Co-Applicant. Funding received for travel to seminars/conferences and/or small personal bursaries will not be considered in this regard.

c) Show evidence that they possess the capability and authority to manage and supervise the research team.

Applicants may apply to one, or both tiers.

Where an applicant fails to meet the eligibility criteria, the application will be deemed ineligible and will not be accepted for review. The HRB will contact the Lead Applicant if this situation arises.

Co-Applicants

All applications must include a cross-border Co-Applicant.

Co-Applicants will be asked to select whether they are a Researcher, Knowledge User, Data Controller/Processor, or PPI contributor Co-Applicant for the purpose of the proposed research.

Up to a maximum of 8 Co-Applicants can be included.

A Co-Applicant has a well-defined, critical, and substantial role in the conduct and steering of the proposed research. Co-Applicants from outside the island of Ireland are welcome where this is appropriately justified in terms of added value for the project. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards their own salary if they are in salaried positions. However, researchers in contract positions/independent investigators, knowledge user and PPI contributor Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to the research for the duration of the award (up to a maximum of 8 Co-Applicants can be listed).

Each Co-Applicant must confirm their participation and is invited to view the application form online. The terms of any co-application should be determined early, and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up co-application agreements.

Applicants may add additional Co-Applicants since their Stage 1 Expression of Interest submission at Stage 2 Full application stage; however, the total number should not exceed 8.

Collaborators

All applications must include an NCI Collaborator.

The NCI Collaborator may be an intramural or extramural researcher depending on the specific proposal and area of expertise required. Any NCI Collaborator proposed as part of the Applicant Team, would be expected to be involved and well-connected with and part of the wider NCI community actively engaged within NCI structures, committees, working groups, frameworks, networks, designated cancer centres etc. to meet eligibility expectations.

If the NCI collaborator proposed is part of an NCI designated cancer centre and connected/ participating within the wider NCI networks this meets eligibility expectations. The aim is to increase trans-Atlantic NCI and cross-border collaborations.

Solely, being a current or previous grant holder from NCI without ability to further demonstrate connectivity within the wider NCI community and structures would not meet eligibility requirements.

A Collaborator is an individual or an organisation who will have an integral and discrete role in the proposed research and is eligible to request funding from the award when properly justified. Named Collaborators may include investigators or organisations from outside the Republic of Ireland, but an individual or organisation should only be named as Collaborator if they are providing specific contributions (either direct or indirect) to the activities. A Collaborator may provide training, supply

samples or kits, provide access to specific equipment, specialist staff time, staff placements, access to data and/or patients, instruments or protocols, industry know-how, or may act in an advisory capacity. Collaborators can come from a range of backgrounds such as academia, the private sector, a healthcare organisation, the charity sector, or a patient group (up to a maximum of 10 Collaborators can be listed).

Applicants may add additional Collaborators since Stage 1 Expression of Interest when submitting their Full Application at Stage 2; however, the total number should still not exceed 10.

Profile details must be provided for ALL Collaborators. In addition, each Collaborator must complete a Collaboration Agreement Form. A template Collaborator Agreement form will be made available on GEMS for download.

If access to samples, vulnerable population groups, healthy volunteers or patients, data, databases, or a link to an existing national or international study (e.g., an existing cohort or longitudinal study) are an integral part of the proposed project, evidence of commitment and access must be demonstrated by having the Data controller or key Gatekeeper of a study included as a Collaborator.

The applicant team will be asked to describe any relevant agreements that they have entered into to facilitate their partnership working. The terms of any collaboration should be determined early, and relevant agreements should be in place by the onset of the project.

The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, ownership and copyright, access and sharing of data and samples etc. when working up Partnership proposals.

Funded Personnel

Applicants must demonstrate that the level, expertise, and experience of proposed research personnel matches the ambition and scale of the project and that they possess the necessary breadth and skills in all methodological areas required to deliver the proposed programme of work. Alignment between personnel requested and the proposed project should be demonstrated. Roles and responsibilities of funded personnel must be differentiated and clear.

This scheme is not framed as a training initiative for PhD candidates.

Host Institution

A HRB Host Institution is a research-performing organisation approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all HRB award schemes. The **Host Institution for the award** is normally that of the **Lead Applicant** but it may be another organisation/institution designated by the research team, where it is clearly justified. In order to be eligible to apply for funding, an Institution must be an **approved** HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for

research performing organisations to be approved as HRB Host Institutions can be found on the HRB website[6].

Please note that this call **is** open to HRB Host Institutions from **Republic of Ireland and Northern Ireland**

At Full Application stage, Host Institution Letters of Support must be provided for **(1) all Lead Applicants in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary.** The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information:

[*Host Institution – insert name*] which is the host institution of [*applicant – insert name*] confirms that [*applicant – insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB All Ireland Cancer Consortium (AICC) 2024 award as a contract researcher; (ii) has an independent office and research space/facilities for which they is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

Application, Review Process and Assessment Criteria

Grant E-Management System (GEMS)

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie/).

The application must have been reviewed and approved by the signatory approver at the research office (or equivalent) in the Host Institution before it is submitted to the HRB. Therefore, applicants should ensure that they give the signatory approver sufficient time before the scheme closing date to review the application and approve it on GEMS. Please note that many host institutions specify internal deadlines for this procedure.

The HRB is committed to an open and competitive process underpinned by international peer review. To ensure the integrity of the assessment process, conflict of interest and confidentiality are applied rigorously in each stage of the process.

Review Process

The AICC 2024 will use a two-stage application process consisting of:

Stage 1 – Open call for Expressions of Interest submitted as Pre-Applications from both tiers

[6] *http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/*

The pre-application consists of an Expression of Interest (EOI) which will focus on a high-level project strategy, added value of the project, governance, project management and project budget.

Pre-applications will be reviewed by the HRB and HSC R&D +/- NCI to review alignment with cancer consortium research areas, cancer strategies and proposed collaborations. Applicants will be shortlisted based on these criteria.

Shortlisted applicants will then be invited to Stage 2 to submit a Full Application (Stage 2)

Stage 2 – Full Application (by invitation only)

Information provided in the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie) at Pre-Application stage will feed automatically into the invited full application forms.

The Lead Applicant (LA) will have the opportunity to make revisions from pre-application to full application stage (e.g., addition of expertise/partner, revision of targeted profession/disciplines for training, strengthening the stakeholder participation, etc.). However, full applications should reflect a development of the relevant pre-applications rather than a radically different approach.

Full applications, once submitted, will undergo a **two-step** assessment process as follows:

- Applications will be initially checked for eligibility by HRB staff members.
- Following the initial eligibility check, each eligible application submitted to this scheme will undergo a public review process followed by an international panel review process according to the assessment criteria.

Panel Review

An international grant selection Panel will be convened. Panel members are selected based on the range of applications received and the expertise and skillset needed (e.g., research area and methodological and analytical approaches, coaching and mentoring, knowledge translation/applied health research, etc.). Panel members are assigned as lead and secondary reviewers to specific applications.

Panel members have access to the application. HRB staff members are present at the meeting to clarify any procedural aspects for the Chair or Panel members and to take notes for the feedback process.

The Panel will review the strengths and weaknesses of the application relating to the assessment criteria detailed below. Successful applicants are expected to score well in all review criteria. While PPI is not a stand-alone assessment criterion, it may influence scores under any criterion as relevant to the application.

At the end of the panel meeting, a final score is collectively agreed for each application and then they will be ranked according to score.

Gender balance of the Lead Applicant will be considered where required to prioritise proposals with the same scores in the Panel ranking list.

The recommendations of the Review Panel will be presented for approval to the HRB Board. When the Board of the HRB has approved the process and recommendations, HRB staff will contact the Lead Applicants and Host Institutions to notify them of the outcome. Applicants will receive feedback in the form of a summary of Panel Members' discussion and written review comments. These will be issued to the Lead Applicant following Board approval.

Assessment Criteria

The following assessment criteria will be used to assess applications by the panel reviewers. Successful applications will be expected to achieve **highly across all criteria.**

Added value of investment

- Proposed investment has clear added value above and beyond any research activities, collaboration or networking currently taking place.
- HRB support complements and leverages other investments.
- Existing cancer research capabilities and collaborations in Ireland harnessed to ensure impact for patients.

Quality and relevance of proposed award activities

- Investment is strategic and targeted to boost all island and trans-Atlantic collaboration and partnerships in cancer research and innovation.
- Spectrum of activities/supports is appropriate to increase cancer research in areas of need.
- Coordinated approach to engagement with the NCI evident.
- Proposed work is prioritised and phased appropriately.
- Budget and resource details proposed are clear and appropriate.

Strength of collaboration and team

- Suitable applicant team, with complementary expertise and experience including appropriate stakeholders to maximise impact for patients.
- Roles and responsibilities of proposed team are clear.
- Proposed team can deliver on objectives of the award.
- Representation from Ireland, Northern Ireland, and NCI Contributors as appropriate.
- Clear, strong links with relevant HIs/Hospitals/research groups/patient organisations evident in governance arrangements.
- Accessibility and suitability of facilities, infrastructure, and other supports, as appropriate.

Panel members will be advised to take PPI approaches into consideration under any of the assessment criteria if considered relevant.

Timeframe

Date	
01 March 2024	Call Opening Pre-Application Stage
26 April 2024 @13:00	Call Closing Pre-Application Stage
May 2024	Shortlisting Review Meeting
04 June 2024	Call Opening Full-Application Stage
26 July 2024 @13:00	Call Closing Full-Application Stage
Sept 2024	Panel Review Meeting
Sept 2024	Panel recommendations presented to HRB Board
Oct 2024	Contracting stage (subject to approval)
01 Nov 2024	Earliest start date

For further information on the AICC 2024 scheme contact:

Dr Chiara Mizzoni email: cmizzoni@hrb.ie

Project Officer

Research and Innovation Infrastructures

Research Strategy and Funding

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's Policy on Appeals on funding decisions is available at https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-appeals/.

Appendix I: Detailed Guidance on the Application Form

Please review carefully as changes may have been made from the guidance provided at Stage 1 Expression of Interest Pre-Application stage. Information from the Pre-Application stage will feed automatically into the AICC 2024 Stage 2 Full Application form and can be edited as required.

Only registered users of the GEMS system can apply for grants. In order to submit an online application to the HRB, applicants are required to register at the following address: *https://grants.hrb.ie*

Please refer to the GEMS Technical Guidance Notes, available on the left-hand column of your GEMS profile homepage, for further information.

The Lead Applicant must create the application, and it can then be jointly completed with named co-applicants or on behalf of a group/organisation.

- Lead Applicants can register on GEMS and they will receive an email to confirm their registration and log in details. The Lead Applicant can then add information on their contact and CV details in the 'Manage My Details' section of their GEMS account.
- Lead Applicants previously registered on GEMS can login to their GEMS account and update any information regarding their basic CV details in the 'Manage my details' section.

Once logged in to GEMS applicants are taken directly to the Home Page which is the starting point to create a new Grant Application.

When the Lead Applicant opens a new application in GEMS, they will be asked to complete a check list of mandatory questions. In order to access the application form, the Lead Applicant must satisfy the conditions of this check list. The checklist for the All-Ireland Cancer Consortium 2024 is as follows:

Requirements	
I have read the Full Application Guidance Notes for the AICC 2024 call.	✓
I am clear about the role of the authorised signatory in the nominated Host Institution, and I am aware that I need to build sufficient time into the application process for the HI to access, review and approve my final proposal for submission to the HRB through the GEMS system.	✓
By submitting this application, I agree to (a) sharing of my data outside of the European Economic Area (EEA) for the purpose of international peer review, and (b) the use of my data for assessment of my application; monitoring of successful awards; and evaluation of HRB's approach to funding and investment in research, in line with HRB policies and as detailed in the AICC 2024 Call Guidance Notes.	✓
I confirm I hold a post in a HRB recognised Host Institution in the island of Ireland as an independent investigator or (2) I am a clinician who holds an adjunct position in a HRB recognised Host Institution, or (3) I am an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award.	✓

The Lead Applicant will be then able to select the Host Institution and Notify the Authorised Signatory before starting the application. Further details for completing each of the main sections of the application are provided below.

Host Institution

A **HRB Host Institution** is research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all of the HRB's award schemes. The **Host Institution for the award** is normally that of the Lead Applicant but it may be another organisation/institution designated by the research team, where it is clearly justified. Information is available on the HRB website on the current approved Host Institutions and on the application process for research performing organisations to be approved as HRB Host Institutions[7].

In GEMS you will be asked to identify a Host Institution (from this list) and type it in full (do not use acronyms such as UCD, TCD, UG). Once you have entered the first 3-4 characters of the Host Institution, you will be assisted with auto-select options. It is important that the HI name is entered accurately and in full as an incorrect entry may result in delays in attaining Host Institution approvals.

It is important to note that the Host Institution for the award is the body in charge of the financial and administrative co-ordination of the AICC grant award. This must be one of the collaborating academic institutions.

Signatory Notification (within Host Institution)

Once the Host Institution is selected at the initial stages of application creation this will allow the Lead Applicant to notify the **authorised signatory** (Dean of Research or equivalent person authorised to endorse research grant applications for the Host Institution) in that Host Institution of the Lead Applicant's intention to submit an application to this scheme. The signatory's details are pre-populated in the system, so the applicant just needs to click 'NOTIFY' within GEMS. **We recommend that you notify the HI signatory of your intention to apply for the full application as soon as possible in the application process**. The signatory will receive an email from GEMS with the name and email details of the Lead Applicant and if they have any queries or clarifications, they can engage directly with the applicant to resolve them. The HI signatory must confirm their willingness to participate as HI for the application through GEMS and once they do this a PDF of the application will be available for them to review with a view to them ultimately approving the final version of the proposal for submission to the HRB.

Only the Host Institution for the award, which is the body in charge of the financial and administrative co-ordination of the AICC grant award is required to authorise the submission of the application to the HRB.

[7] https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institutions.

1. Lead Applicant Information

GEMS Profile Details – Basic CV information

Details are requested about the **Lead Applicant** including their position and status (contract or permanent), their supervisory experience, and whether they are seeking salary-related costs. Please note that a **letter of support from the Host Institution** must be provided if the Lead Applicant is on a contract position.

Host Institution Letters of Support must be provided for (1) all Lead Applicant- in a contract position and (2) Researcher Co-Applicants in a contract position who are seeking their own salary. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre must include the following information; *[Host Institution – insert name] which is the Host Institution of [applicant – insert name]* confirms that *[applicant/co-applicant – insert name]*: (i) holds an employment contract which extends until *[insert date]* or will be recognized by the Host Institution upon receipt of the HRB ILP award as a contract researcher; (ii) has a dedicated office and research space/facilities for which they is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team.

Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

Should the award not fund any additional post-graduate students or post-doctorate researchers and the co-applicant researcher is not required to mentor on this award, the HI is not required to endorse point (iii).

The Lead Applicant's **contact and CV** details (Name, institution, present position, employment history, profession, and ORCID iD) are managed in 'manage my details' section of GEMS and are automatically included in any application created involving that individual. You are asked to select your 5 most relevant publications for this application.

Note: The HRB is an ORCID member. Leadership team members are encouraged to include an ORCID iD by updating their GEMS profile under 'Manage my Details' and this will feed automatically into the application form. You have also the option to import your publication record from ORCID iD in addition to PubMed. Please note this is not a mandatory field for submitting the application. For more information and to register please see https://orcid.org/.

ORCID iD

To include an ORCID iD in your application please update your GEMS profile under 'Manage my Details'. For more information and to register please see https://orcid.org/.

Publications and Funding Record

Publications are automatically included in any application created involving the Lead Applicant Researcher. To update this information, edit the 'My Research Outputs' section on the Home page of GEMS. You can then use the Publication selection tool in the relevant section of the application form to select your **5 most relevant publications** for this application.

You should also include your **5 most relevant funding awards** as Principal Investigator or Co-Applicant.

For the purpose of this application form, Funding Record details should be added directly on to the application form and will not be pulled through from the 'manage my details' section of GEMS.

Additional evidence of experience and expertise relevant to this application

The Lead Applicant can describe any additional experience or expertise that will provide evidence of their ability to successfully lead the proposed project. This section focuses on the applicant contribution to the generation of knowledge, new ideas and hypotheses, and tools. This can include how ideas and research results were communicated (written and verbally), as well as funding and awards received. The word limit is **400 words**.

Note: Research outputs can include datasets, software, publications, commercial or entrepreneurial or industrial products, educational products, clinical practice developments, policy publications, and other similar items. These should be examples of rigorous science following high standards, that are reproducible, and others can build upon.

Please do not include information related to H-indexes, impact factors, or any type of metric that refers to the journal, publisher, or publication platform. The scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published.

Breaks from research

In this section the Lead Applicant may want to mention breaks from research, such as statutory leave, secondments, flexible work arrangements or other relevant changes (e.g., sector or discipline) that may have affected or influenced their progression as researcher. Please state the period and the reason. The word limit is **150 words**.

Gender

Please select:

- Man
- Woman
- Nonbinary
- Another gender identity
- Prefer to not disclose

This question is included with the application form in light of the **HRB Gender Policy**. The HRB has the responsibility to support everyone to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. The information is for HRB internal use only.

2. Co-Applicant Details (to be included for each Co-Applicant)

The Lead Applicant can add **up to 8 Co-Applicants** to an application by entering their name on GEMS. If the Co-Applicant is already registered on GEMS, the system will find them and will allow the Lead Applicant to select them. Alternatively, a Co-Applicant can be added manually by entering their name and email details. GEMS will send them an email with login details for completing the registration process and will inform them that they have been invited by the Lead Applicant to participate on the application as a Co-Applicant. **Registered Co-Applicants** can decide whether to accept or reject their participation and **must consent to the application being submitted jointly in their name**. If a Co-Applicant rejects participation on an application the Lead Applicant is informed and may revise the application accordingly. Co-Applicants who accept participation in an application will be able to edit the application. **The system will flag if another user is working on the application form at the same time via a pop-up warning. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data, but it is advisable that they contact the other person directly to avoid losing data when applying the override function.**

Each Co-Applicant can manage their **contact and CV details** (Name, contact information, institution or organisation, present position, employment history, profession, membership details of professional bodies, and ORCID iD) under 'Manage my Details' section of GEMS and this information will be automatically included in any application that involves this individual.

Co-Applicants will be asked to select whether they are a Researcher, Knowledge User, Data Controller, Data Processor or PPI contributor Co-Applicant for the purpose of the proposed research. If a Co-Applicants contributes from more than one perspective, please select the dominant role.

2.1 Researcher Co-Applicants

Researcher Co-Applicants will be asked to provide additional information in the application form, including their **5 most relevant publications** in peer-reviewed journals, their **relevant funding record** (past or current grants held, including HRB grants), and their **current position and status** (contract or permanent).

Additional evidence of experience and expertise relevant to this application

The Researcher Co-Applicant can describe their contribution to the generation of knowledge, new ideas and hypotheses, and tools. This can include how ideas and research results were communicated (written and verbally), as well as funding and awards received. The word limit is **400 words**.

Breaks from research

In this section the Researcher Co-Applicant may want to mention breaks from research, such as statutory leave, secondments, flexible work arrangements or other relevant changes (e.g., sector or discipline) that may have affected or influenced their progression as researcher. Please state the period and the reason. The word limit is **150 words**.

For Researcher Co-Applicants holding contract positions who are seeking their own salary, a **Letter of Support** from the Host Institution must also be included.

2.2 Knowledge User Co-Applicants

Knowledge User Co-Applicants will be asked to provide information regarding **their expertise and experience in influencing decision making within knowledge user organisation(s).**

Knowledge User Co-Applicants will be asked to highlight their previous and current roles in influencing decision-making processes within their organisation or other relevant organisations. They should also use this space to highlight their specific experiences and expertise for the Knowledge User Co-Applicant role in relation to the proposed research. The word limit is **300 words**.

Knowledge User Co-Applicants will be asked to provide information regarding potential **Additional experience and expertise relevant to this application.** For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health, evidence of Public and Patient Involvement in your knowledge user role, and roles/responsibilities as a constructive and effective change agent. The word limit is **300 words**.

2.3 Data Controller Co-Applicants

Data Controller Co-Applicants will be asked to provide additional information including the name of the data set(s) they are data controller for. Data Controller Co-Applicants may wish to include here any additional experience or expertise that will support the application. For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health. If they have research expertise/experience Co-Applicants may wish to include relevant outputs such as publications, funding secured or other outputs. The word limit is **400 words**.

2.4 Data Processor Co-Applicants

Data Processor Co-Applicants will be asked to provide additional information including the name of the data set(s) they are involved in processing. Data Processor Co-Applicants may wish to include here any additional experience or expertise that will support the application. For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health. If they have research expertise/experience Co-Applicants may wish to include relevant outputs such as publications, funding secured or other outputs. The word limit is **400 words**.

2.5 PPI Contributor Co-Applicants

PPI Co-Applicants should provide some information regarding their experience and expertise relevant to this application. For example, they may wish to include relevant experience as a service user or carer, relevant experience from their personal lives, prior experience in PPI or any other useful background information. The word limit is **400 words**.

Researcher Co-Applicants will be asked to provide additional information in the application form, including their **5 most relevant publications** in peer-reviewed journals, their **relevant funding record** (past or current grants held, including HRB grants), and their **current position and status** (contract or permanent).

3 Collaborators' Details

The Lead Applicant can add **up to 10 collaborators** per application. Unlike Co-Applicants, the information for Collaborators **is not** automatically drawn from the 'Manage my Details' section of GEMS but must be entered by the Lead Applicant. The Lead Applicant must enter **contact and CV details** for all Collaborators including name, contact information, institution or organisation and present position.

In addition, for each Collaborator a signed **Collaboration Agreement Form** must be provided. A template Collaboration Agreement Form is available for downloaded from GEMS. Forms must be completed, signed, dated, and uploaded where indicated on HRB GEMS. Please label each form with the name of the relevant Collaborator. Electronic signatures are acceptable on letters/forms that are uploaded on GEMS.

4 Project Details

4.1 Project Title

You are asked to provide a title that clearly describes the research to which this application is related. This should be descriptive and concise and should reflect the aim of the project. There is a **200 characters** maximum limit.

Title Acronym

This is optional.

4.2 Project Duration and Start Date

AICC 2024 is a two-tier scheme.

Tier one of the scheme is designed to allow for smaller scale applications which involve ***pilot projects or mapping activities*** up to a maximum individual award, exclusive of overheads totalling ***€100,000*** over a two-year duration.

Tier two is for specific, targeted ***projects or potential training initiatives*** which may occur over a 3-year period. This is exclusive of overheads and should not exceed ***€330,000***.

Overheads are calculated at 25% for desk-based research or 30% for all other research.
Please select which tier you wish to apply for:

Tier 1 ☐

Tier 2 ☐

4.3 Project Lay Summary

This lay summary is similar to the Project Abstract in that you are asked to describe what you propose to do, why you think it is important and how you are going to go about conducting, analysing and drawing conclusions from the research. The difference is that it **needs to be written as a plain English summary** such that it is clear, easy to understand, and is easily accessible to a lay audience. It should not be copied and pasted from elsewhere in the application. The lay summary may be used when providing information to the public with regards to the variety of research funded by the HRB and may be posted on the HRB website. A well-written lay summary will enable Panel members to have a better understanding of your research application. The word limit is **300 words.**

4.4 Abstract

This should be a succinct summary of the proposed research project. The aims and main objectives should be conveyed with clarity and what the programme is expected to establish should be described. Ideally the abstract provides a clear synopsis of your proposal. The word limit is **300 words**.

4.5 Keywords

Please enter up to **5 keywords** that specifically describe your research project.

5 Project Description

Please ensure that your application is focused, and that sufficient evidence is provided to enable the grant selection panel members to reach a considered judgement as to the quality of your research application, its potential health impact and its feasibility.

The Project Description must include:

- Research Question
- Proposal Strategy
- Current Knowledge, Background to the Area, Relevance and Knowledge Gap

- Overall Aim
- Objectives and Deliverables (plus Gantt chart or alternative)
- Research Design and Methodological Approach
- Details for applications that include a 'pre-clinical' study
- Impact Statement
- IP Considerations
- Dissemination and Knowledge Translation Plan
- Project Management
- FAIR Data Management and Stewardship
- Public and Patient Involvement (PPI) in the Research Project
- Gender and/or Sex Issues in the Research Project
- Potential Safety Risks and Ethical Concerns
- Biobanking (where appropriate)
- Project Description Figures (where appropriate)
- References

5.1 Priority Areas

Please select which priority area your proposal is aligned to.

- Cancer Care Delivery and Survivorship
- Clinical Research and Trials
- Genomic and Precision Medicine

5.2 Research Question

Clearly state the research question behind the proposed work. The word limit is **50 words.**

5.3 Proposal Alignment

Outline the proposal's alignment with cancer strategies for both/either the Republic of Ireland and/or Northern Ireland and its alignment with one of the AICC research priority areas (Cancer care delivery and survivorship *or* Clinical research *or* Genomics and precision medicine). The word limit is **300 words.**

5.4 Current Knowledge, Background, Relevance and Knowledge Gap

Describe the background to the research application and detail the size and nature of the issue to be addressed. **We expect that applicants reference evidence supporting the case for the project that has been gathered systematically**, i.e., as systematic reviews or other evidence synthesis formats. Simple literature overviews are not sufficient. Evidence synthesised systematically should include evidence of (1) a systematic identification of previous work, (2) critical appraisal, (3) synthesis of the evidence and (4) interpretation of findings. Where available, include a description of any pilot work, professional and consumer consensus studies already undertaken.

Please reference any documented need for this area of research, including information on burden on health or the healthcare system. Have any potential users of research outputs been involved in identifying the research question (e.g., patients, healthcare professionals, policymakers)? Explain why this research is both important and timely. Show how your research will add to the knowledge base/advance the state of the art in this area. Be aware that the peer reviewers reading your application are based outside of Ireland, so it is important to describe the healthcare delivery context in Ireland when discussing issues around need (including specific needs of any under-represented groups), relevance, timeliness, and feasibility. The word limit is **1200 words**.

5.5 Overall Aim

Please state the overall aim of the research project. The word limit is **100 words.**

5.6 Objectives and Deliverables

Please add a minimum of 3 research objectives. Objectives should be SMART (**S**pecific, **M**easurable, **A**chievable, **R**ealistic and **T**ime-bound). For each objective, list a subset of deliverables which will be used to monitor progress throughout the lifetime of the award if successful. Objectives/deliverables should be mapped against estimated completion timelines in a Gantt chart, and any milestones highlighted.

The word limit is **60 words for each objective and 150 words for the deliverables**.

You must upload a **Gantt chart** which lists the above objectives and deliverables against the estimated timelines for completion, together with any additional milestones/key dates. Please note that the preparation and submission of Data Management Plans should also be added as deliverables/milestones of the Project.

5.7 Research Design and Methodological Approach

Summarise the proposed research plan, providing descriptions of individual work packages and describe how they integrate to form a coherent research application.

Include details of the general experimental approaches, study designs and techniques that will be used. Include details on all stages of the study design including rationale for sampling strategy, justification of sample size and power calculation, details on the design chosen, the methods of data collection, measures, instruments, and techniques of analysis for quantitative and qualitative designs, outcomes measures and plans for data analysis/data management.

Where research involves human participants, please describe the selection criteria and rationale for participant selection considering the relevant population for the issue under study. Are under-served populations/groups considered?

Please justify any exclusions based on age or sex/gender of participants.

Show how your research design will allow you to answer your research question.

Notes:

You are strongly advised to seek advice and input from an experienced **research design and statistics** expert in advance of submitting your application. **Discrepancies and incorrect approaches in this section represent the most common source of feedback in unsuccessful HRB applications.**

Power calculations and sample sizes (including for animal studies) must be described and justified, and aligned with the study aim, objectives and goals and the context of the study.

Explain in detail how new techniques and/or or high-risk studies will be managed and suggest alternative approaches should these fail.

Where new methods are being developed, arrangements for establishing validity and reliability should be described. Examples of non-standard questionnaires, tests, etc. should accompany the application or their content be clearly indicated.

Useful links and resources are summarised in Appendix III.

The word limit is **4500 words.**

Has an iteration of the proposed research been submitted to any HRB award scheme in the last 3 years? Yes/No

(If yes)

Award Scheme:

Year of previous submission:

Please briefly describe the changes that have been made to the application. Have the recommendations from the previous peer, panel, or public review you received influenced the changes you have made? The word limit is **300 words**.

5.8 Details for applications that include a 'pre-clinical' study

For applications which contain one or more elements of a 'pre-clinical' study, in addition to details given in Section 5.5 Research Design and Methodological Approach, as to number of animals used and how this was determined, applicants must provide further information as follows:

Provide appropriate evidence with regard to the relevance of the proposed animal species or model compared with humans (e.g., target expression distribution and primary structure; pharmacodynamics; metabolism and other pharmacokinetic aspects; or cross reactivity studies using human and animal) Any available relevant systematic reviews should be considered.

and

Justify and document in detail the choice of species/model relative to the pathology and/or human condition (aetiology, pathophysiology, symptomatology, and response to therapeutic intervention)[8] [9] **and**

Describe how the proposed pre-clinical work correlates and aligns with any planned future stages of the research in humans even if not part of this application. If your project involves the use of animals, provide sound scientific justification for their use, explain why there are no realistic alternatives, and demonstrate that the numbers proposed will allows meaningful results to be obtained from the research.

Useful links including to the EU Reference Laboratory for alternatives to animal testing and the PREPARE guidelines (developed to promote animal alternatives, reduce waste and increase the reproducibility of research and testing) are referenced in Appendix III.

Give details of the proposed sex of the animals, and rationale for the numbers of each sex[10][11]. Experiments should use the smallest possible number of animals required to answer the research question and should ensure that distress and suffering are avoided wherever possible. Applicants are strongly advised to consult with their animal care team in their HI when planning animal studies. Links to an online tool created to aid researchers including incorporating sex into study design and the ARRIVE checklist can be found in Appendix III.

Note: In some pre-clinical studies where, due to the species-specific nature of the clinical product (e.g., some vector-expressed human transgenes or human derived cellular products) testing in animals would not prove informative or appropriate, alternative *in vitro* pre-clinical models may be proposed, but detailed justification must be provided.

Note: Where no relevant species exists, the use of homologous proteins or the use of relevant transgenic animals expressing the human target may be the only choice but, in every instance, a detailed justification of the pre-clinical model must be provided.

The word limit is **1000 words.**

5.9 Impact Statement

Describe the anticipated outputs and outcomes of the proposed research. Please provide details on the likely impact of this research on human health and wellbeing indicating the anticipated timescale for any proposed benefits to be realised. Please consider areas for impact such as, but not limited to, providing the basis for new/improved healthcare innovations, influencing policy and practice, increasing enterprise activity. Outline what steps are necessary for these impacts to be realised. Please clearly describe the added value of this proposal in the context of the All-Ireland(north/south)

[8] https://www.fda.gov/media/88625/download

[9] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf

[10] https://science.sciencemag.org/content/364/6443/825/tab-figures-data

[11] Female rodents are not more variable than male rodents: A meta-analysis of preclinical studies of fear and anxiety - PubMed (nih.gov)

cancer environment. This statement should be specific and provide information that the external reviewers will find helpful in assessing the potential impact of the proposed research. Impact statements should be written primarily in plain English. The word limit is **400 words**.

5.10 IP Considerations

The Lead Applicant together with the Host Institution has a duty to the public to ensure that discoveries and advancements in knowledge arising from any award are translated for public benefit including but not limited to commercial development of new therapies, diagnostics, materials, methodologies, and software for health[12]. Please consult with the relevant Technology Transfer Office for advice on this section, where appropriate.

Please describe any current Intellectual property (IP) that will be relevant for the study and whether such IP assets are held by the applicants, and/or others outside the research team. Such IP might include software, checklists, scales, protocols, guidelines, questionnaires, or medicinal products for example. Has relevant background IP for your study been identified? If IP is required, is there freedom to operate, such that this research can eventually be translated? What arrangements are in place to manage IP during the study, and ensure it is protected (if appropriate) prior to dissemination? Do you foresee any barriers to use of IP in order for the research outputs to be adopted? The word limit is **300 words**.

5.11 Dissemination and Knowledge Translation Plan

Include a clear dissemination and knowledge translation plan to indicate how the research outputs you anticipate producing during and after your project will be disseminated and shared and made openly accessible, in line with HRB Open Access Policy[13]. Research outputs include peer-reviewed publications, non-peer reviewed publications and conference proceedings, reports, policy briefings, guidelines, training materials and so on. Protection of Intellectual Property should be considered before data are disseminated[14].

Applicants are advised to consider the following:

- The HRB has a mandatory Open Access publication policy; demonstrate how you plan to make all publications open access.
- Who are the various audiences and communities that need to be targeted if these results are to have any impact? What is your dissemination plan to address this, how will these audiences be reached?

[12] Ireland's National IP Protocol 2019: A Framework For Successful Research Commercialisation: Policies and resources to help industry and entrepreneurs make good use of public research in Ireland

[13] https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/open-access

[14] All HRB Host Institutions must subscribe to the National Intellectual Property Protocol 2019, 'A Framework For Successful Research Commercialisation', prepared by Government/Knowledge Transfer Ireland to ensure transparent and consistent procedures for managing Intellectual Property from publicly funded research.

- Describe any plans for technology transfer.
- Describe how the findings of this research will be publicised to the HSE or international health community/organisations in a manner that will optimise impact on health policy and/or practice.
- Please reference aspects of the project/study undertaken to maximise chances of adoption beyond the term of the award.

Types of publication routes include[15]:

Green Route: publishing in a traditional subscription journal. Articles are 'self-archived' (added) to a repository (institutional or external subject-based) and usually made available after an embargo period, which is set by the publisher.

Gold Route: publishing in an open access or hybrid journal. Articles' processing charges (APCs) are required so that the article is openly available immediately on publication and can be added to a repository (institutional or external subject-based).

HRB Open Research: rapid open peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee. (www.hrbopenresearch.org/).

The word limit is **500 words**.

5.12 Project Management

Please describe how the research project will be managed. The role of each applicant team member and research personnel member should be clearly outlined. Describe any oversight, advisory or governance structures that are crucial to delivery of the project, including a steering committee or data safety and monitoring committee if applicable. Outline the processes that will be put in place to ensure that the project is well managed, commenting on project management, meetings schedules, financial management etc. Describe contingency plans, including how you intend to manage any risks to the delivery of the project. The word limit is **600 words**.

5.13 FAIR Data Management and Stewardship

Describe the general approach to data management and stewardship that will be taken during and after the projects, including who will be responsible for data management and data stewardship. With the support of data stewards or other data-related services support in the institution (typically library and ICT and digital service, etc) all Applicants should address as much as possible the following points below regarding the management of the research data to be generated and/or re-used during the research project.

[15] https://www.jisc.ac.uk/guides/an-introduction-to-open-access

Please consider the FAIR Guiding Principles for scientific data management and stewardship: **F**indability, **A**ccessibility, **I**nteroperability, and **R**eusability[16].

1. **Data description and collection or reuse of existing data**: (a) What is the type, format and volume of data? (b) How will the data be collected, created or reused?
2. **Documentation and data quality**: (a) What metadata and documentation will accompany the data? (b) Will you make sure globally resolvable unique, persistent identifiers are in use (e.g DOI)? (c) What data quality control measure do you use?
3. **Storage and backup**: (a) How will data be stored and backed up during the research? (b) How will you take care of data security and personal data protection?
4. **Ethical and legal compliance, codes of conduct**: (a) If personal data are involved, how will you manage compliance with legislation on personal data and security? (b) How will you manage legal issues, such as IPR, copyright, and ownership? Which legislations are applicable? (c) Which ethical issues and codes of conduct are there and how are they taken into account?
5. **Data sharing and long-term preservation:** (a) How and when will you share the data? (b) How do you select data for preservation and where will data be preserved long term (e.g. data repository, archive)? (c) What methods or software tools are needed to access data? (d) How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?
6. **Data management responsibilities and resources:** (a) Who (for example role, position, and institution) will be responsible for data management (i.e., the data steward)? (b) What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR?

The word limit is **500 words**.

5.14 Public and Patient Involvement (PPI) in the Research Project

*The HRB recognises that the nature and extent of meaningful public involvement is likely to vary depending on the context of each study. Please note PPI does **not** include the recruitment of study participants in research projects. It also does **not** include work aimed at raising awareness of the public around research, such as media publications of research findings, and outreach activities such as open days in research facilities.*

Useful resources including practical examples of involving members of the public in your research can be found in Appendix III. Please be aware there are PPI Ignite Network offices in some host institutions.

Are you including PPI in your application?

If Yes

16 Wilkinson, M. D. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci. Data 3:160018 doi: 10.1038/sdata.2016.18 (2016).

Please describe all PPI at each stage of the research cycle:

- Identifying and prioritising the research question
- Design
- Conduct
- Analysis
- Oversight
- Dissemination

For each stage, please include the purpose of this involvement and where applicable how PPI has influenced/changed what work has been planned.

This section should be a succinct summary of public involvement activities. Provide information on the individuals/groups and the ways in which they will be involved. PPI contributors should be representative of the relevant people and communities impacted by the research topic. **Where members of the public or patients are involved, they should be compensated for their time and contributions; this should be reflected in the project budget.**

Please ensure to provide more detail in other sections as appropriate.

Important: The PPI section needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience.

If No

Please explain why PPI is not relevant to your project.

The word limit is **600 words**.

5.15 Gender and/or Sex Issues in the Research Project

A key objective of the HRB is to strive for gender balance in Irish health research. We encourage a balanced participation of genders in all research activities.

Please note this section is intended to focus researchers on the **research content**, and **not** the gender balance within the research team.

Please identify and explain how you address sex and/or gender issues for this project.

Are there potential sex (biological) considerations for this research?

Are there potential gender (socio-cultural) considerations for this research?

If so, outline how sex and/or gender analysis will be integrated in the design, implementation, evaluation, interpretation, and dissemination of the results of the research application.

If not, you must clearly demonstrate why it is not relevant to the research application; have you done a literature search to confirm this?

Please see Appendix III for resources on gender and sex considerations in research applications.

The word limit is **400 words.**

5.16 Potential Safety Risks and Ethical Concerns

Please address any potential risk and/or harm to patients or human subjects/participants in the research, if relevant. Please highlight any potential ethical concerns (including work involving animals) during this study and/or at follow-up stage. Describe any potential ethical concerns that may arise as a result of this research, even if not part of this application, and how you propose to deal with them. If the proposed research includes vulnerable groups, what additional considerations are there for these participants? The word limit is **400 words**.

5.17 Biobanking

Does your application include an element of biobanking? Y/N

If yes, please describe how biobanking within this project will be in compliance with international best-practice ethical considerations and the General Data Protection Regulation, in particular in relation to consent.

You must submit a completed **Infrastructure Agreement** form with details of the biobank. Please describe how you will ensure good practice for biobanking components in this project, with particular regard to quality of sample collection, processing, annotation and storage. Please reference relevant guidelines/standards you will use. Where material will be obtained or stored for a future research purpose, or where you will use material previously obtained for another purpose, please refer to the latest Recommendation of the Council of Europe[17]. Some useful links are in Appendix III. The word limit is **400 words**.

5.18 Project Description Figures

A file upload option is available to include an attachment to support your Project Description**.** A **maximum of 5 figures**, which can be a combination of images, graphs, tables, scales, instruments, or surveys, may be uploaded as a single document on HRB GEMS. They must not be embedded within the text of the Project Description. Additional references should not be included here. The maximum size is **2MB**. Files should be doc, docx, or pdf.

5.19 References

A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of **30 publications**. Please enter references in the same format.

For publications:

[17] https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

Gallagher PA, Shoemaker JA, Wei X, Brockhoff-Schwegel CA, Creed JT. Extraction and detection of arsenicals in seaweed via accelerated solvent extraction with ion chromatographic separation and ICP-MS detection. Fresenius J Anal. Chem. 2001 Jan 1;369(1):71-80. PMID: 11210234.

For book and printed source citations:

Farrell M, Gerada C and Marsden J (2000) *External review of drug services for the Eastern Health Board*. London: National Addiction Centre.

For data citations:

Authors, year, article title, journal, publisher, DOI

Author(s), year, dataset title, data repository or archive, version, global persistence identifier

6 Details of Research Team

6.1 Lead Applicant's Role

Please indicate the current commitment to research/clinical/teaching/other as proportion of a full time equivalent (FTE).

Give an outline of the proposed role of the Lead Applicant in this project on a day-to-day basis. Please indicate below the proposed amount of time to be dedicated to working on **this project** as a proportion of a full time equivalent (FTE). The word limit is **250 words.**

6.2 Co-Applicant's Role

For each Co-Applicant, please identify the type of Co-Applicant they are here (Researcher Co-applicant, Knowledge User Co-applicant, Data Controller Co-applicant, Data Processor Co-Applicant, or PPI Co-applicant) and outline their role in this project on a day-to-day basis, including the amount of time to be dedicated to working on this project as a proportion of a full time equivalent (FTE). The word limit is **250 words**.

6.3 Collaborator's Role

For each Collaborator, please outline their role in the project. The word limit is **100 words**.

6.4 Personnel

Give full details of all personnel to be funded through this project, including the Lead Applicant if relevant. State the proportion of a full time equivalent (FTE) each person will spend on the project and describe what aspects of the proposed research they will be involved in over the lifetime of the project. Note that you must justify the nature of all research personnel relative to the scale and complexity of the project (please see section 6.1.5 Funded Personnel for more guidance on alignment between the chosen personnel and the project). If funding is requested for known

personnel, please include the following details: Name, present position, academic and professional qualifications. The word limit is **400 words**.

7 Project Budget

Please provide a summary and justification of the costs and duration associated with the project.

A **full detailed breakdown** of **costings** and **justification for all funding** is required for items listed under each subheading within GEMS.

Note: You are strongly advised to seek guidance from the research office/finance office in the Host Institution before completing this section of the form. The HRB will not provide additional funding in the case of either under-estimates or over expenditure**.**

The total funding available will be:

Tier 1: €100,000 over 24 months exclusive of overheads

Tier 2: €330,000 over 36 months exclusive of overheads

Allowable costs include:

1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with Host Institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scales for academic researchers http://www.iua.ie/research-innovation/researcher-salary-scales/. Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure. **Applicants should include annual pay increments for staff and related costs (pension contribution and employer's PRSI contribution) in the budget.** In line with the proposed new pay agreement for State employees please apply a salary contingency of 3% from 1st October 2024 onwards. Please note this contingency should be applied cumulatively year on year. **Note:** The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators
b) Employer's PRSI	Employer's PRSI contribution is calculated at 11.15% of gross salary.
c) Employer Pension Contribution	Pension provision up to a maximum of 20% of gross salary will be paid to the Host Institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.

2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, data access costs etc. Maintenance costs of animals are allowed for pre-clinical animal models only. Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, Clinical Research Facilities support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form'. The following costs are ineligible and will not be funded: training courses/workshops with the exception of training in public and patient involvement in research, inflationary increases, cost of electronic journals.) **Note:** Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.

3. PPI Costs	Costs associated with public and patient involvement in research. Some examples are:
	• Compensating PPI contributors for their time (for example for time spent reviewing material/ participation in advisory groups). This can be as:
	  ○ a cost for their expertise, e.g. as hourly rate, under PPI costs or
	  ○ as salaries under personnel which should be labelled PPI contributors under salaries.
	• Travel expenses for PPI contributors.
	• Costs associated with PPI contributors attending conferences, workshops, or training.
	• PPI facilitator costs.
	• Compensation of public or patient organisations for their time.
	• Room hires for PPI events/meetings.
	• Hospitality for PPI events/meetings.
	• Companionship or childcare costs for PPI contributors while attending events, meetings, etc.
	• Training in PPI in research.
	• PPI contributors supported by salaries as research staff or co-applicants, where applicable in a scheme, should be listed and justified under the personnel heading.
	
	All costs must be in line with the Host institutions policies, practices and HRB Terms and Conditions.

4. Equipment	Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €10,000. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e., overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified, and should not exceed €1,200. All costs must be inclusive of VAT, where applicable. Depending on the nature of the project, high spec computers may be eligible and clear justification and rationale for the costs requested must be provided. All costs must be inclusive of VAT, where applicable.
5. Dissemination Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge translation plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[18]. Please list

[18] http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/

	dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary). **Publications:** Typically, the average HRB contribution towards publication costs is €1,750/per article or **HRB Open Research**: rapid open peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee. (www.hrbopenresearch.org) free of charge. **Conferences:** We envisage that conference costs will be typically around €500 for national conference and €1,500 for international conference per person and year.
6. FAIR Data Management Costs	Costs related to data-related and data management activities in line with best practice of data management and stewardship and the FAIR principles **incurred during the lifetime of the project**. Please see table below for further guidance.

Overhead Contribution will be added by HRB staff during contract negotiations for successful applications. It is not requested as part of the application budget. In accordance with the HRB Policy on Overhead Usage[19], the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment, and capital building costs) for **laboratory, clinically or field-based research** and 25% of Total Direct Modified Costs for **desk-based research**.

The following items are included in the overhead contribution: recruitment costs, bench fees, office space, software, contribution to gases, bacteriological media preparation fees, waste fees, bioinformatics access. Therefore, these should not be included in the budget as direct costs.

7.1 Co-Funding Budget Commitment

If applicable, please include details on any co-funding commitment and indicate the total amount secured from this Co-Funding.

Co-Funding Commitment Letter

Please note that a Co-Funding Commitment Letter must be uploaded where co-funding is part of this application. This letter should confirm that the funding contribution is in place. It is not a mandatory application requirement to secure co-funding.

7.2 Other Funding

Please indicate if you have submitted this, or a similar application, to another HRB scheme or funding body. If this application has been submitted elsewhere, please indicate which HRB scheme or funding body, project title, result of submission or when outcome is expected and the amount of award. The word limit is **200 words**.

[19] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-usage-of-research-overheads/

8 Ethical Approval and Approvals for Use of Animals

Ethical approval is required for all research work funded by the HRB that involves human participants, human material (including tissue) or animals (pre-clinical models only). Applicants are responsible for ensuring that all necessary approvals are in place prior to the start of the research.

Applicants should allow sufficient time to obtain ethical and/or competent authority approval and/or animal licenses. if successful, the applicant will be required to complete and submit Approvals Declaration form to the HRB before the initiation of the award.

9 Supporting Documentation

The following documents must be uploaded to complete the application:

Mandatory documents:

- Objectives and Deliverables Gantt Chart

If applicable:

- Letter of Support for Lead Applicant or Co-Applicants in contract positions seeking their own salary
- Collaboration Agreement Form(s) – required for all collaborators
- Infrastructure Agreement Form(s) – required for biobanking and access to Clinical Research Facilities
- Project Description Support file – A maximum of 5 figures which can be a combination of images, graphs, tables, scales, instruments, or surveys

Submission of Applications

The deadline for submission of complete applications is 26 07 2024 at 13:00.

1. After successful validation, the Lead Applicant may submit the application. It will then be routed to the designated signatory at the Host Institution for their approval.
2. If a signatory rejects the application the Lead Applicant will be notified, along with any feedback the signatory has supplied.
3. The application can then be re-submitted; it will be returned to the signatory and will continue through the approval process as before.
4. On completion of the final approval by the Host Institution signatory, a grant application number is assigned to the application.
5. The application automatically gets submitted to the HRB through GEMS for consideration for funding.

Please note that the HRB will not follow up any supporting documentation related to the application, such as Host Institution's Letters of Support, Collaborator Agreement Form, Gantt

charts etc. It is the responsibility of the Lead Applicant to upload all supporting documentation prior to submission. If the documentation is not received by the HRB on time, in the correct format or is not properly signed or submitted, the application will be deemed ineligible without further review.

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's Policy on Appeals on funding decisions is available at https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-appeals/.

Appendix II: HRB Funding Policies and Procedures

Access and support from research infrastructures

Applications availing of the advice, research design, data management services and/or other forms of support from a Clinical Research Facility/Centre (CRF/CRC), other infrastructure (e.g., Centre for Applied Medical Imaging, CAMI, Centre for Support and Training in Analysis and Research (CSTAR), HRB-Trials Methodology Research Network (HRB-TMRN), Cancer Groups, National clinical trials office (NCTO), CTNs or a biobank) are required to provide additional information detailing the scope and nature of the engagement (this includes national and international facilities, Units, and networks where justified).

An **Infrastructure Agreement form** will be requested as part of the application addressing the nature/scope of the service or collaboration, the rationale behind the choice of facility/centre/network and any costs associated with the project (including those provided as in-kind contributions). Applications proposing research with patients which do not detail advice and/or support from a CRF/CRC/CTU will be asked to justify why they have not done so.

Public and Patient Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public and patients in the research that we fund[20]. Public and patient involvement in research means that the public and patients are involved in planning and doing research from start to finish and help tell the public about the results of research. PPI, as defined here, is distinct from and additional to activities which raise awareness, share knowledge, and create a dialogue with the public, and it is also distinct from recruitment of patients/members of the public as participants in research.

PPI represents an active partnership between members of the public and patients and researchers in the research process. This can include, for example, involvement in the selection of research topics, assisting in the design, advising throughout or at specific decision points of the research project or in carrying out the research.

PPI contributors should be actively involved and part of decision making. Involving members of the public in research can improve quality and relevance of research. It can:

- Provide a different perspective – even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition.
- Help to ensure that the research uses outcomes that are important to the public.
- Identify a wider set of research topics than if health or social care professionals had worked alone.

[20] https://www.hrb.ie/funding/funding-schemes/public-and-patient-involvement-in-research/

- Make the language and content of information such as questionnaires and information leaflets clear and accessible.
- Help to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants.
- Help you increase participation in your research by making it more acceptable to potential participants.

In addition to improving relevance and quality of research, it ensures that research is influenced by broader principles of citizenship, accountability, and transparency. PPI is an ethos as well as a practice. It should be context-specific and should aim to ensure that all voices are heard. Where members of the public or patients are involved, they must be compensated for their time and contributions.

In the application, you are asked to describe any public involvement in your research throughout the various stages of identifying and prioritising the research question, the research design, conduct, analysis, and dissemination. We recognise that the nature and extent of active public involvement is likely to vary depending on the context of each study or award. PPI contributors should be named as Co-applicants where justified by their level of involvement.

For guidance and support on PPI in your research please consult with the PPI Ignite Network Ireland or your Host Institution. The PPI Ignite Network Ireland has offices located in the following seven Host Institutions: DCU, NUIG, RCSI, TCD, UCC, UCD, UL.

FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support open research[21] and open publishing directly through the HRB Open Research platform[22]. The HRB is driving the making of research data **FAIR** (**F**indable, **A**ccessible, **I**nteroperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles[23] provide a guideline for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals. For researchers, the move to FAIR and open data, where applicable, means researchers should consider data management issues and find suitable data repositories at the research planning stage. Applicants will have to provide information about their plans for data management and data sharing at application stage.

In line with the HRB's policy on management and sharing of research data[24], all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three

[21] http://www.hrb.ie/funding/policies-and-principles/open-research/

[22] https://hrbopenresearch.org/

[23] https://www.nature.com/articles/sdata201618

[24] https://www.hrb.ie/fileadmin/user_upload/HRB_Policy_on_sharing_of_research_data.pdf

months after the award start date, and a final updated version of the DMP with the last annual report.

The DMP will need to be submitted alongside a certification of completion from the designated representative(s) within the Host Institution e.g. data steward

Applicants will have to provide an outline of their plans for data management and data sharing in the application inclusive of the costs associated to the plan.

The timing for completion and submission of the DMPs must be also included among the objectives and deliverables of the programme. Please submit a draft DMP within the first three months of the grant start date to DMP@hrb.ie. This should be followed by a final DMP version submitted at the end of the grant.

General Data Protection Regulation

The **General Data Protection Regulation** (GDPR) came into force on 25 May 2018. As a result, the applicant team will be asked through the HRB online grant management system GEMS to **confirm you understand** that personal data provided as part of this application, including but not limited to CV information, may be shared with person(s) based outside of the European Economic Area (EEA) for the specific purpose of obtaining peer reviews of this application. International reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Individual peer reviewers are selected for their specific expertise in relation to submitted applications and can be based anywhere in the world.

Furthermore, by confirming participation, you will be asked to confirm you understand that HRB uses the information you provide (regarding all applicant team members) to consider your application, contact you about your application, and if you are successful, to manage your grant throughout its lifetime in accordance with HRB general T&C for research awards. This will include contacting you with regard to monitoring of progress through written reporting and other means e.g., interim review. We will publish some basic information on successful awards including PI, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended, we will continue to keep your information on file (in accordance with HRB policies) to allow us to evaluate the outcomes, outputs and impacts of HRB investment in your research.

Please note that we will also use information associated with *unsuccessful* applications for a number of the purposes outlined above such as generating general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment e.g., demographics of applicants, research areas of applicants. Similarly, we will use the information provided about people employed on awards to help evaluate our career support and capacity building initiatives.

The Health Research Regulations

Following the implementation of GDPR, a regulation for health research known as the Health Research Regulations 2018 (S.I. 314) has been implemented, with further amendments made in 2019 (S.I. 188) and 2021 (S.I. 18)[25]. These regulations outline the mandatory suitable and specific measures for the processing of personal data for the purposes of health research. They further set out that explicit consent is a mandatory safeguard that must be obtained from individuals when using their personal data for health research. Where it is not feasible to obtain explicit consent, an application for a consent declaration can be made to the Health Research Consent Declaration Committee[26].

Research on Research

The HRB is developing its approach to research on research (RoR) with the aim of enhancing the evidence base for HRB research funding practices. We may also collaborate with researchers on request regarding specific RoR questions. Should your application become of interest to such a study, the HRB will seek your consent for the use of your information.

HRB Gender Policy

In line with international best practice, the **HRB Gender Policy**[27] recognises the responsibility of the HRB to support everyone to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. To ensure fairness and equality to all applicants, each funding application received will be assessed as outlined in the call guidance documentation for that particular funding round. To ensure gender balance in decision-making, the HRB aims to reach the international best practice target of 40% of the under-represented gender in all HRB panels where possible. Gender will also be considered when appointing the position of Panel Chair.

Conflict of Interest

Conflict of interest rules *are applied rigorously*. Where a conflict of interest exists, the reviewer is requested to inform the HRB immediately so that an alternative reviewer may be appointed. International peer reviewers will not provide comments or scores on any application on which they have a conflict of interest.

Reviewers must adhere to high standards of integrity during the peer review process. They must respect the intellectual property of applicants and may not appropriate and use as their own, or disclose to any third party, ideas, concepts, or data contained in the applications they review.

[25] http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

[26] https://hrcdc.ie/

[27] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-gender-in-research-funding/

Appeals Procedure

The HRB's Policy on Appeals on funding decisions is available at https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-appeals/.

Privacy Policy and Retention Policy

To understand why we collect the information we collect and what we do with that information, please see our Privacy[28] and Retention Policies[29].

[28] https://www.hrb.ie/about/legal/privacy-policy/

[29] https://www.hrb.ie/fileadmin/user_upload/HRB_Document_retention_policy..docx

Appendix III: Resources/Useful Links

STUDY DESIGN FOR INTERVENTIONS

"Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework" by Eldridge S. *et al.*

http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0150205

"The PRECIS-2 tool: designing trials that are fit for purpose" by Louden *et al.*

http://dx.doi.org/10.1136/bmj.h2147

"A process for Decision-making after Pilot and feasibility Trials (aDePT): development following a feasibility study of a complex intervention for pelvic organ prolapse" by Bugge C *et al*.

http://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-14-353

"Developing and Evaluating Complex Interventions" by MRC, UK

www.mrc.ac.uk/complexinterventionsguidance

"Process evaluation of complex interventions: Medical Research Council guidance" by Moore GF. e*t al.*

http://dx.doi.org/10.1136/bmj.h1258

"Using natural experiments to evaluate population health interventions: Guidance for producers and users of research evidence" by MRC, UK

www.mrc.ac.uk/naturalexperimentsguidance

Consort 2010 Statement: updated guidelines for reporting parallel group randomised trials

www.consort-statement.org

SQUIRE Guidelines: provides a framework that authors can use when developing applications or writing research articles about quality improvement

www.squire-statement.org

HIQA Guidelines for the Economic Evaluation of Health Technologies in Ireland (2018)

https://www.hiqa.ie/reports-and-publications/health-technology-assessment/guidelines-economic-evaluation-health

HIQA Guidelines for the budget Impact Analysis of Health Technologies in Ireland (2015)

https://www.hiqa.ie/system/files/Guidance_on_Budget_Impact_Analysis_of_Health_Technologies_in_Ireland.pdf

HIQA Guidelines for Evaluating the Clinical Effectiveness of Health technologies in Ireland (2011)

http://www.hiqa.ie/system/files/HTA-Clinical-Effectiveness-Guidelines.pdf

STUDY REGISTRATION

International Clinical Trials Registration Platform (run by the WHO)

http://apps.who.int/trialsearch/Default.aspx

European Clinical Trials Database (EudraCT): database of all regulated clinical trials which commenced in the EU from 1 May 2004

https://eudract.ema.europa.eu/results-web/

US National Library of Medicine database: database of privately and publicly funded clinical studies – regulated and unregulated – conducted around the world

https://www.clinicaltrials.gov/

REPORTING

COMET (Core Outcome Measures in Effectiveness Trials) Initiative: development and application of agreed standardised sets of outcomes, known as 'core outcome sets'

http://www.comet-initiative.org/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies

https://www.equator-network.org/library/

Registry of Research Data Repositories

http://www.re3data.org/

Zenodo Data Repository (OpenAIR)

https://zenodo.org/about

https://zenodo.org/

EVIDENCE SYNTHESIS

Evidence Synthesis Ireland: aims to build evidence synthesis knowledge, awareness and capacity among the public, health care institutions and policymakers, clinicians, and researchers on the Island of Ireland.

https://evidencesynthesisireland.ie/

The Cochrane Library: online collection of databases in medicine and other healthcare specialties which summarise and interpret the results of medical research.

www.thecochranelibrary.com

The Campbell Collaboration: promotes positive social and economic change through the production and use of systematic reviews and other evidence synthesis for evidence-based policy and practice.

https://www.campbellcollaboration.org/

The Campbell Collaboration UK & Ireland: hub at Queens University Belfast.

https://www.qub.ac.uk/research-centres/CampbellUKIreland/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies.

http://www.equator-network.org/resource-centre/library-of-health-research-reporting/

CLINICAL RESEARCH INFRASTRUCTURES

All Ireland Hub for Trials Methodology Research

http://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/TheAll-IrelandHubforTrialsMethodologyResearch/

Centre for Advanced Medical Imaging, St James' Hospital Dublin

http://www.3tcentre.com/

Centre for Support and training Analysis and Research (CSTAR)

http://www.cstar.ie

Children's Clinical Research Unit

https://www.nationalchildrensresearchcentre.ie/childrens-clinical-research-unit/apply-for-support/

Clinical Research Support Unit, **Limerick**

https://www.ul.ie/hri/clinical-research-support-unit

Clinical Research Centre, Royal College of Surgeons in Ireland

https://www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/clinical-research-centre

Clinical Research Facility, University College Dublin

http://www.ucd.ie/medicine/ourresearch/researchenvironment/ucdclinicalresearchcentre/

Clinical Research Support Centre (Northern Ireland)

http://www.crsc.n-i.nhs.uk/

HRB Clinical Research Facility, Cork (HRB CRFC)

http://www.ucc.ie/en/crfc/

HRB Clinical Research Facility, Galway (HRB CRFG)

http://www.nuigalway.ie/hrb_crfg/

HRB Critical Care Clinical Trials Network (HRB Critical Care CTN)

ICC-CTN (iccctn.org)

HRB Irish Network for Children's Clinical Trials (in4kinds)

In4kids

HRB Primary Care Clinical Trials Network (HRB Primary Care CTN)

Primary Care Clinical Trials Network Ireland – HRB PC CTNI (primarycaretrials.ie)

HRB Trials Methodology Research Network (TMRN)

http://www.hrb-tmrn.ie

The National Clinical Trials Office (NCTO)

Email trials-ireland@ucc.ie

https://ncto.ie/

Wellcome Trust-Health Research Board Clinical Research Facility, St James's Hospital (WT-HRB CRF SJH)

http://www.sjhcrf.ie/

BIOBANKING

Council of Europe Recommendation of the Committee of Ministers to member States on research on biological materials of human origin (2016)

https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

BBMRI-ERIC is a European research infrastructure for biobanking

https://www.bbmri-eric.eu/

OECD Guidelines on Human Biobanks and Genetic Research Databases

http://www.oecd.org/science/biotech/44054609.pdf

ISBER Best Practices for Repositories

https://www.isber.org/page/BPR

Molecular Medicine Ireland Biobanking Guidelines

http://www.molecularmedicineireland.ie/resources/biobanking-guidelines/

NCI Best Practices for Biospecimen Resources (2016 version)

https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf

PUBLIC AND PATIENT INVOLVEMENT IN RESEARCH & RESEARCH PRIORITIES

The National PPI Ignite Network

https://ppinetwork.ie/

NIHR PPI resources

https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437

Patient-Centred Outcomes Research Institute (PCORI)

http://www.pcori.org

Public Involvement Impact Assessment Framework: Provides tools for successful involvement of members of the public in research projects and for assessment of impacts.

http://piiaf.org.uk/

NIHR Payment guidance for researchers and professionals

https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392

European Patient Forum Value + Handbook: For Project Co-ordinators, Leaders and Promoters on Meaningful Patient Involvement.

http://www.eu-patient.eu/globalassets/projects/valueplus/doc_epf_handbook.pdf

The James Lind Alliance Priority Setting Partnerships: Research priorities in disease areas set jointly by patients, clinicians, and researchers.

http://www.jla.nihr.ac.uk/

Campus Engage: Supporting Irish HEIs to embed civic engagement in their work. Includes resources, how-to-guides, and case studies for engaged research.

http://www.campusengage.ie/what-we-do/publications/

UK Standards for Public Involvement: The six UK Standards for Public Involvement provide clear, concise statements of effective public involvement against which improvement can be assessed.

https://sites.google.com/nihr.ac.uk/pi-standards/home

The Involvement Matrix: A tool for researchers/project leaders to promote collaboration with patients in projects and research.

https://www.kcrutrecht.nl/involvement-matrix/

The Evaluation Toolkit: is a resource designed for practitioners of the health sector, produced after the completion of a rigorous systematic review of patient and public engagement evaluation tools.

https://ceppp.ca/en/evaluation-toolkit/

GRIPP2 reporting checklists: Tools to improve reporting of patient and public involvement in research

https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-017-0062-2#Tab1

USE OF ANIMALS IN RESEARCH

EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) (reviews of available non animal models)

https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam_en

Experimental Design Assistant (EDA) (online tool for design of animal experiments)

https://eda.nc3rs.org.uk/

PREPARE (Planning Research and Experimental Procedures on Animals: Recommendations for Excellence) guidelines

https://norecopa.no/prepare

ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines

https://arriveguidelines.org/

SYRCLE (Guidance and training on systematic review of animal studies)

https://www.syrcle.network/

PROSPERO (Register for systematic reviews including animal studies)

https://www.crd.york.ac.uk/PROSPERO/

GENDER AND/OR SEX ISSUES IN RESEARCH

Examples of case studies in Health & Medicine where gender/sex in research matters

http://genderedinnovations.stanford.edu/case-studies-medicine.html

Gender Toolkit in EU-funded research for examples and guidance

http://www.yellowwindow.be/genderinresearch/downloads/YW2009_GenderToolKit_Module1.pdf

Sex/Gender Influences in Health and Disease

https://orwh.od.nih.gov/sex-gender/sexgender-influences-health-and-disease

Methods and Techniques for Integrating Sex into Research

https://orwh.od.nih.gov/sex-gender/methods-techniques-integrating-sex-research

NIH Policy on Sex as a Biological Variable

https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable

DATA MANAGEMENT AND SHARING AND FAIR PRINCIPLES

Digital Curation Centre: How to develop a data management and sharing plan and examples DMPs.

http://www.dcc.ac.uk/resources/data-management-plans/guidance-examples

FAIR data principles FORCE 11

https://www.force11.org/fairprinciples

UK Concordat on Open Research Data (July 2016)

https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

FAIR at the Dutch centre for Life sciences

https://www.dtls.nl/fair-data/

Registry of Research Data Repositories

http://www.re3data.org/

RESEARCH DATA MANAGEMENT PLANS

Data Stewardship Wizard created by ELIXIR CZ and NL

https://dmp.fairdata.solutions/

DMPonline of the Digital Curation Centre (DCC), UK

https://dmponline.dcc.ac.uk/

DMPTool of University of California Curation Center of the California Digital Library (CDL), USA

https://dmptool.org/

RDMO Research Data Management Organiser of the German Research Foundation, Germany

https://rdmorganiser.github.io/en/

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

KNOWLEDGE TRANSLATION RESOURCES

Health Service Executive Research & Development Main Page

https://hseresearch.ie/research-dissemination-and-translation/

Health Service Executive Research & Development: Knowledge Translation, Dissemination, and Impact A Practical Guide for Researchers

https://hseresearch.ie/wp-content/uploads/2021/04/Tools-and-templates-.pdf

Integrated Knowledge Translation (iKT) NUI Galway

https://www.nuigalway.ie/hbcrg/ikt/

The Canadian Institutes of Health Research: Guide to Knowledge Translation Planning

https://cihr-irsc.gc.ca/e/45321.html

Training Institute for Dissemination and Implementation Research in Health: Open Access Course

https://cancercontrol.cancer.gov/is/training-education/TIDIRC-open-access

IMPLEMENTATION SCIENCE RESOURCES

Centre for Effective Services

https://www.effectiveservices.org/resources/implementation

UCC Implementation Science Training Institute

https://www.ucc.ie/en/cpd/options/medhealth/cpd1778uccimplementationsciencetraininginstitute/

European Implementation Collaborative

https://implementation.eu/resources/

CO-CREATION RESOURCES

ACCOMPLISSH Guide to impact planning

https://www.accomplissh.eu/publications-and-deliverables

Working together to co-create knowledge: A unique co-creation tool – Carnegie UK Trust

https://www.carnegieuktrust.org.uk/publications/working-together-to-co-create-knowledge-a-unique-co-creation-tool/

INFORMATION ON PERSISTENT IDENTIFIERS

DOI: List of current DOI registration agencies provided by the International DOI Foundation

http://www.doi.org/registration_agencies.html

Handle: Assigning, managing and resolving persistent identifiers for digital objects and other Internet resources provided by the Corporation for National Research Initiatives (CNRI)

http://www.handle.net/

PURL: Persistent Identifiers developed by the Online Computer Library Center (OCLC). Since 2016 hosted by the Internet Archive

https://archive.org/services/purl/

URN: List of all registered namespaces provided by the Internet Assigned Numbers Authority (IANA)

https://www.iana.org/assignments/urn-namespaces/urn-namespaces.xml

DATA REPOSITORIES

Registry of Research Data Repositories

http://www.re3data.org/

Data centers accredited by the German Data forum according to uniform and transparent standards (Germany)

https://www.ratswd.de/forschungsdaten/fdz

Zenodo Data Repository (OpenAIR)

https://zenodo.org/

OTHER USEFUL LINKS

Tool that helps to select and apply a license to a resource, provided by Creative Commons

https://creativecommons.org/choose/