INVESTIGATOR-LED PROJECTS (ILP) 2024

Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	01 August 2023
Application Closing Date	11 October 2023 @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 authorised 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

1 Introduction

The Health Research Board (HRB) Strategy[1] sets out the organisations' objective to invest in research that delivers value for health, the health system, society, and the economy. The Investigator-Led Projects scheme (ILP) scheme provides support for high-quality, investigator-led research to create new knowledge that, over time, will help to address the major health challenges in society and have an impact on tomorrow's health and social care. Here we interpret the term "health challenges" in its widest sense, including issues such as to understand better how to maintain and promote health and well-being, how to prevent or treat illness, and how best to organise the health and social care system.

The ILP scheme is complementary to the two other general project grant schemes under the HRB strategy: the Applied Partnership Awards (APA) and the Definitive Interventions and Feasibility Awards (DIFA).

2 Aim and Objectives

The Investigator-Led Projects scheme aims to support highly innovative and internationally competitive investigator-led projects that can respond to existing and emerging challenges for health and social care.

The objectives are to:

- Fund research that addresses important questions for health and social care
- Support high quality, internationally relevant research
- Add to the knowledge base at an international level
- Support research that will lead to an improved visibility and standing for Ireland and Irish researchers

3 Major changes since the last round

In recognition of the rising costs of research, the overall budget has been increased. The maximum total value on an award including overhead contribution will now be €430,000 (previously €370,000), with a maximum of €330,000 for direct costs (previously approx. €285,000).

Applicants are no longer asked to include overhead contributions into their budget. This will be added by the HRB team during contract negotiations.

This scheme is not framed as a training initiative for PhD candidates. Where candidates for a higher degree are proposed to work on projects, Lead Applicants must show evidence of careful consideration ensuring a good training experience for the PhD candidate.

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

4 Scope of Call

The ILP scheme provides funding for clearly defined research projects in:

i. Patient-oriented research (POR)

ii. Population health research (PHR)

iii. Health services research (HSR)

Further guidance and details of the research areas within these remits for the ILP scheme can be found in Appendix II.

We expect that evidence supporting the case for the project 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.

In addition to the eligible remit, you should note that in this scheme the HRB will **not fund:**

- Applications involving basic biomedical research.
- 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, surveys, needs assessments or technology development (although these elements may be part of an integrated 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[2] for a definitive intervention. Such studies are supported through the HRB **Definitive Intervention and Feasibility Awards** (DIFA) scheme.
- Applications which are solely or predominately developing the infrastructure for biobanking, databases or patient registers without a predominant research element.
- 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 tobacco industry.

[2] 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

- 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.

Please note that applicants can include trials methodology research or can propose work to develop a healthcare intervention. Such work may include some initial testing of the intervention in order to generate proof of concept data and thus have the basis for developing a feasibility study. Applicants could then apply to HRB or another funder to support a feasibility study as a next step. In such cases applicants must consult with the appropriate clinical research infrastructure supports (such as the Clinical Research Facilities), to ensure that the work done will allow them to develop a feasibility study subsequent to the ILP-funded research.

Where an application is outside the scope of the scheme, the application will be deemed ineligible by the HRB at initial eligibility review or by the review panel at the panel meeting.

5 Funding Available, Duration and Start Date

The ILP scheme will provide funding for projects in POR, PHR and HSR up to a maximum of **€330,000** direct costs **(exclusive of overheads)** per award. The HRB plans to commit in the region of €12 million to the ILP 2024 awards. Quality permitting it is expected that a minimum of 27 awards will be funded. Awards will have a duration of between **24 and 48 months**.

The award will provide support for research-related costs including salary for research staff, running costs, PPI costs, FAIR data management costs, equipment and dissemination costs, and overheads contributions. The overheads contribution will be added by HRB staff during contracting stage. **The maximum total award including overhead contribution will be €430,000.**

Note: The Investigator-Led Projects 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, and reviewers will thoroughly assess the level of funds and timeframe requested when reviewing the application.

The earliest start date of the Grant is September 2024.

6 Eligibility Criteria

This call **is** open for Host Institutions from Northern Ireland.

6.1 Applicant Team

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

Applicants must have a suitable track record and demonstrate clearly that the research team contains the necessary breadth and depth of expertise in all methodological areas required for the development and delivery of the proposed project. Appropriate multi- and inter- disciplinary involvement in the research team is essential and where relevant, experts in research design and statistics, health economics, health service research, behavioural science, qualitative research methodologies, psychology, sociology etc. should be included as Co-Applicants or Collaborators.

Co-applicants and Collaborators from outside the island of Ireland are welcome where their participation clearly adds value to the project. The HRB expects that applicants will collaborate, where appropriate, with partner organisations such as universities, hospitals, health agencies, relevant local or international organisations and/or voluntary organisations. The HRB promotes the active involvement of members of the public and patients in the research that we fund (see Public and Patient Involvement (PPI) in Research for further details). **PPI contributors** are welcome as **Co-Applicants or Collaborators depending on their role within the project**. Although not a requirement for this scheme, the involvement of **knowledge users** (national or international) as co-applicants or collaborators is welcome where this adds value to the research proposed.

A **knowledge user** is defined as one in a position of authority to influence and/or make decisions about health policy or the delivery of services and can act to ensure that the findings of the research will be translated to influence decision making and change within their (or other) organisations. This is typically managers, policy makers, clinicians, health professionals or others who are in a position to make significant changes to policy or practice. Knowledge user organisations may be Government departments, HSE, other agencies, hospitals or hospital groups, community healthcare organisations, local government, voluntary organisations, research charities, patient/consumer groups or other organisations involved in making decisions regarding the management, structuring and/or delivery of practice or policy in the Irish health and social care system.

6.1.1 Lead Applicant

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 programme. 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.

Only one application per Lead Applicant to this scheme will be considered.

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 in the event that this situation arises.

As signatory of the DORA Declaration[3], the HRB is committed to supporting a research environment where importance is placed on the intrinsic value and relevance of research and its potential impact in society (HRB - Declaration on Research Assessment).

6.1.2 Co-Applicants

Co-Applicants will be asked to select whether they are a **Researcher, Knowledge User or PPI Contributor** co-applicant for the purpose of the proposed research. Up to a maximum of **6 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 his/her 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,

[3] Home | DORA (sfdora.org)

depending on their role and percentage of time dedicated to the research for the duration of the award **(up to a maximum of 6 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.

6.1.3 Collaborators

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)**.

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.

A **'Data controller'** refers to a person, company, or other body that decides how and why a data subject's personal data are processed. If two or more persons or entities decide how and why personal data are processed, they may be 'joint controllers', and they would both share responsibility for the data processing obligations[4].

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.

[4] https://www.dataprotection.ie/sites/default/files/uploads/2019-07/190710%20Data%20Protection%20Basics.pdf

6.1.4 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. Where candidates for a higher degree are proposed to work on projects, Lead Applicants must carefully consider:

- The complexity, scale, objectives, and dependencies of the project.
- The suitability of such project in terms of delivering a clearly identifiable original research project or the potential difficulties in clustering various pieces of work packages for a PhD or Masters thesis. The skills, expertise and experience level required to carry it out.
- Any requirements and/or restriction relating to the PhD or Master's candidate's registration with the Host Institution, and this should be accounted for when determining the start date of the award.

If proposing a PhD candidate, please note the following:

1. The Lead Applicant should clearly put in place appropriate supervisory arrangements with a supervisory team in place, which may include Co-Applicant(s), if appropriate.
2. The Lead Applicant, with input from the Host Institution and should provide a Host Institution's letter of support that sets out the Host Institution's support and the strategy to ensure proper training and development of the PhD candidate and successful completion of the PhD thesis are fulfilled.
3. Lead Applicants must budget for four years funding for PhD candidates.

PhD candidates should be enrolled in a structured PhD programme, at the Institution where they will be registered or through the SPHeRE PhD programme[5], which is Ireland's national research training programme for Population Health, Policy, and Health Services Research.

7 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,

[5] https://www.sphereprogramme.ie/ For further information please contact Katherine Walsh katherinewalsh@rcsi.ie

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 Host Institutions from Northern Ireland.

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 ILP 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.

Host Institution Letters of Support must also be provided for applications proposing PhD candidates as part of their team. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include information about the supervisory arrangements and the strategy to ensure proper training and development of the PhD candidate to the successful completion of the PhD thesis.

It is the responsibility of the Lead Applicant to ensure that applications are completed in full, and all necessary documentation is received by the HRB on, or before, the closing dates indicated.

8 Application, Review Process and Assessment Criteria

8.1 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.

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

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.

Applicants must select one of the following three remits, based on which is the best fit for the proposed research:

i. Patient-Oriented Research
ii. Population Health Research
iii. Health Services Research

Applicants are strongly advised to carefully read the guidance and details of the research areas covered by this remit in Appendix II. It is the responsibility of the Lead Applicant to select the most appropriate remit to classify the application. If in doubt, they should contact the relevant project officer (see Section 10 Contacts for further information). The HRB reserves the right to reassign an application between **the three areas** above if that chosen by the Lead Applicant is deemed inappropriate. Where HRB staff members make a decision to reassign an application the Lead Applicant will be informed.

8.2 Review Process

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 two-phase review process.

Phase 1 – International Peer Review, Public Review and Shortlisting

For each application, the HRB aims to receive written feedback from at least three international peer reviewers and two public reviewers.

International peer 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. Peer reviewers will focus on the stated assessment criteria for the call and will provide comments as well as a score which is visible to the HRB and to panel members.

Public reviewers will only assess the quality of PPI in the application and will provide comments and an overall rating which will be shared with the panel. Public reviewers will not provide a score.

Public Reviewers are asked to comment on the following:

- The plain English summary (Lay Summary)
- Relevance of the proposed research question
- PPI in development of and throughout the project
- Making it straightforward for research participants

- Dissemination of the proposed work

The HRB will share the public review feedback with the PPI Ignite Network team in the Host Institution where applicable.

Applications will be shortlisted for considerations by the Panel using the average of the peer review scores. Typically, approximately twice as many applications are shortlisted than are expected to be funded by this call.

Applicant Response

Applicant teams of shortlisted applications will be provided with a time-limited opportunity to respond to peer and public review comments (see Section 9 Timeframe). Neither peer nor public review comments will include any reference to the reviewer's identity. Public review ratings will be shared.

Once notified that the application is short-listed the peer review and public review comments will be made available to the Lead Applicant on their GEMS personal page. The Lead Applicant will have 10 working days only to submit their response through GEMS, and the response has a **maximum word count of 2000 words only for the peer review response** (including references) and **500 words only for the public review response**. No figures can be uploaded. The response will be provided to members of the Review Panel, in advance of the Panel meeting, along with the application, the peer and public review comments and rating. The response to the public review will be given to the public reviewer as a feedback and learning opportunity.

Phase 2 - 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.

Two panels will be used to select applications for funding: one panel for Patient Oriented Research applications, and one panel for Population Health and Health Services Research applications.

Panel members have access to the application, peer and public reviews and the applicants' response. 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 at the next scheduled HRB Board meeting. 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. A summary of Panel Member's comments and the panel discussion comments will be issued to the Lead Applicant following the Board approval stage.

8.3 Assessment Criteria

The following assessment criteria will be used to assess applications **by peer and panel reviewers**. Successful applications will be expected to **rate highly in all criteria**.

Scientific Quality and Innovation (40%)

- Important research question
- Evidence supports need for proposed project
- Design and methodology appropriate
- Project plan and risk mitigation for project delivery

Impact (30%)

- Potential impact on patients, public and/or healthcare system
- Generalisability beyond research setting
- Planned knowledge dissemination and translation

Research Team and Environment (30%)

- Applicant team expertise and experience relevant for project
- Supports, infrastructure, environment
- Project staffing and funding

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

9 Timeframe

Date	
01 August 2023	Call Opening
11 October 2023 @13:00	Call Closing
November 2023 to March 2024	Scientific and public review
mid-April 2024	Applicant Response
May or June 2024	Panel Review Meetings
June 2024	Panel recommendations presented to HRB Board
July/August 2024	Contracting stage (subject to approval)
1 September 2024	Earliest start date

10 Contacts

For further information on the Investigator-Led Projects contact:

Dr Sónia Pereira

Project Officer

Research Strategy and Funding

Health Research Board

E. ILP@hrb.ie

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

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 Note**[7], available on the left-hand column of your GEMS profile homepage, for further information.*

The **Lead Applicant** must create the application, but it can then be jointly completed with named co-applicants.

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 'Manage My Details' section of GEMS.

Lead Applicants previously registered on GEMS can login to GEMS and update any information regarding their contact and CV details in 'Manage my details'.

Once logged in to GEMS applicants are taken directly to the Home page which is the starting point to create a new Grant application. Prior to starting their application, applicants must select POR, HSR or PHR from among the three choices of ILP 2022 remits (please read the Remit of the HRB Grant Selection Panels in Appendix II of the Guidance Notes).

i. Patient-Oriented Research
ii. Population Health Research
iii. Health Services Research

Once the Lead Applicant selects the application remit on 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 Investigator Led Projects is as follows:

Lead Applicant Eligibility	
I have read the Guidance Notes for the ILP 2024 call and reviewed the main changes applied to the ILP 2024.	
I have reviewed the remit of the Grant Selection Panels outlined in Appendix II and I confirm that, to the best of my knowledge, my application falls within the remit of this Panel.	☑
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.	☑

[7] https://research.ie/assets/uploads/2020/05/CCGT-Grant-Application-System-Technical-Guidance-Notes.pdf

Consent	
By submitting this application, I consent 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 **ILP 2024** Call Guidance Notes.	☑

The Lead Applicant will be then able to start the application. Further details for completing each of the main sections of the application form are provided below:

Host Institution

For the purposes of contracting, payment, and management of the award, HRB funds can only be awarded to HRB approved Host Institutions. Please note this call is open for Host Institutions from Northern Ireland. 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 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, NUIG). 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 Host Institution name is entered accurately and in full as an incorrect entry may result in delays in attaining Host Institution approvals.

If you wish to propose a Host Institution which is not on the HRB list, you are advised to contact the HRB at gemshelp@hrb.ie.

Note: In order to be eligible to apply for funding, an Institution must have been approved as a HRB Host Institution no later than two calendar months before the closing date of a call, only pre-approved Host Institutions will appear in this list.

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 the ILP 2024. 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 Host Institution signatory** of your intention to apply 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 to resolve them with the Lead Applicant. The Host Institution signatory must confirm their willingness to participate as Host Institution 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 for submission to the HRB.

1 Lead Applicant's Details

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.

Host Institution Letters of Support must also be provided for applications proposing PhD candidates as part of their team. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include information about the supervisory arrangements and the strategy to ensure proper training and development of the PhD candidate to the successful completion of the PhD thesis.

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 now an ORCID member. Lead applicants 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 your application. 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**.

Please note that additional information regarding supervisory experience, if planning to supervise a student, and their current position and status (contract or permanent) will be requested in the application form.

2 Co-Applicants' Details

The Lead Applicant can add up to 6 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 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**.

Please note that additional information regarding supervisory experience, if planning to supervise a student, and their current position and status (contract or permanent) will be requested in the application form.

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-Applicant

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 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**.

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, present position, employment history, profession and membership details of professional bodies, **Publications and Funding Record** (if applicable) (**five most relevant** publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) relevant to this application where the Collaborator has acted as Principal Investigator or Co-Applicant).

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.

4.2 Project Duration and Start Date

Please indicate the expected length of the proposed project in months (minimum duration of 24 months and maximum duration is 48 months) and the proposed start date. The earliest start date is September 2024.

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 peer reviewers and Panel members to have a better understanding of your research application. The word limit is **300 words.**

4.4 Project Abstract

This should be a succinct summary of the proposed research. This structured summary should clearly outline the background to the research, the aims and hypotheses of the project. The objectives of the project and what the work is expected to establish should be described. It provides a clear synopsis of your application and should set the research application in context. 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 international peer reviewers and 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
- 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 Research Question

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

5.2 Current Knowledge, Background to the Area, 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 evidence supporting the case for the project 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**.

5.3 Overall Aim

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

5.4 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 (e.g., events organised as part of the grant). Please note that the preparation and submission of Data Management Plans should also be added as deliverables/milestones of the Project.

5.5 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 IV.

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.**

5.6 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 IV.

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 IV.

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.**

5.7 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,

[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)

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.

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**.

5.8 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**.

5.9 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.

[12]Ireland 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.

- 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?
- 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**.

5.10 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.**

5.11 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**.

5.12 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 IV. 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**.

5.13 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 IV for resources on gender and sex considerations in research applications.

The word limit is **400 words.**

5.14 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.**

5.15 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 IV. The word limit is **400 words**.

5.16 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.

5.17 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.

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

For publications:

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 a 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, 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 6.1.4 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 Infrastructure and Support

7.1 Host Institution Infrastructure and Support

Describe the infrastructure, facilities, specialist expertise and other support available at the Host Institution and/or at other sites where the research will be conducted. Please include details of critical supports in areas such as statistics, research methods, biobanking expertise or regulatory expertise where this is being provided above and beyond the activities/expertise of members of the research team. The word limit is **400 words**.

7.2 Access to 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 unit (e.g., Centre for Applied Medical Imaging, Centre for Support and Training in Analysis and Research, HRB – Trials Methodology Research Network) or a biobank are required to provide additional information detailing the scope and nature of the engagement (this include national facilities and/or international facilities and units/networks where justified) at research design or implementation stages. The following information must be provided:

- Name and address of the facility/centre/network.
- Information on the nature and stage/s of the input/advice/collaboration/service.
- Rationale for the choice of facility/centre/network.
- How the proposed involvement enables the planned research to be undertaken to the required quality or timescale.

The word limit is **400 words**.

Applications involving patients which do not detail such input, advice and/or support (and where this expertise is not clearly evident within the applicant team) **must provide a detailed justification** as to why they have chosen not to access such support.

An **Infrastructure Agreement Form** must be completed and can be downloaded from GEMS. The Form must be completed, signed, dated, and uploaded on GEMS. Electronic signatures are acceptable for letters/forms that are uploaded on GEMS.

8 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 direct costs available will be €330,000 over 24-48 months. 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.** Health and Social Care Practitioners stepping out from clinical or social care delivery/services to conduct a 4-year PhD degree (the HRB does not longer support MD degrees) are expected to have a contribution to gross salary costs (inclusive of employee's pension contribution) up to a maximum amount of Level 3, Point 1 of the most up to date IUA scale for four years. Please note that the income derived from the PhD salary income is taxable and subject to deductions (Income Tax, USC and PRSI as applicable) under the PAYE system and in no circumstances can this be changed to a stipend. In line with the proposed new pay agreement for State employees please apply a salary contingency of 3% per annum 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 11.05% 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.

d) Student Stipend	A stipend for academic based post graduate candidates in line with current government guidelines as a flat rate, which is currently €19,000 per annum for • up to two years for MSc degrees • four years for PhD degrees The stipend is tax exempt and in no circumstances the stipend can be used to support postgraduate fees. Please note that: • the HRB does not support stipends different than the current national rate (€19K). • for stipends paid in Northern Ireland or overseas, where eligible, the HRB will pay in euro only.
e) Student Fees	The HRB support a maximum contribution to postgraduate fees of €5,500 annually for individuals registered for a higher degree for: • up to two years for MSc degrees • four years for PhD degrees Where the rate of the final year is reduced in line with the Institutional policy (e.g., some institutions might offer 50% reductions in fees in year four) the HRB reserves the right to recover the unspent fees. Please note: • Postgraduate fees are paid at EU level only. The HRB does not support fees for MD degrees.
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[18]. 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, 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	All PPI-related costs for the grant (except salaried personnel), such as but not limited to: • Compensating PPI contributors for their time (for example for time spent reviewing material/ participation in advisory groups) • Travel expenses for PPI contributors • Training in PPI in research • Costs associated with PPI contributors attending conferences, workshops or training • PPI event facilitator costs • Room hire for PPI events/meetings. • Hospitality for PPI events/meetings • Companionship or childcare costs for PPI contributors while attending events, meetings, etc. **Note:** PPI participants supported by salaries, should be listed and justified under the personnel heading. All costs should be in line with Host Institution policies.

[18] The maximum HRB allowable per diem rates for the maintenance of the most common strains of small animals are: mice (€0.50), other laboratory rodents (€1) and rabbits (€2). All per diem rates are inclusive of VAT. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis.

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[19]. Please list 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[20], 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 or clinically 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.

Additional guidance to FAIR Data Management Costs

People	Staff time per hour for data collection, data anonymisation, etc
	Staff time per hour for data management/stewardship support, training, etc
Storage and computation	Cloud storage, domain hosting charge
Data access	Costs for preparing data for sharing (e.g., anonymisation)

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

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

Deposition and reuse	Costs for depositing research data and metadata in an open access data repository
	Defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please further explain

Notes	The HRB is currently not covering the cost of long-term preservation of data
	This list is not exhaustive and aims to provide examples only of eligible costs

8.1 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.

8.2 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.

9 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 as a copy of such approvals must be submitted to the HRB before the initiation of the award. It is suggested that these are sought in parallel to the submission of the application to the HRB.

10 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.
- Letter of Support for applications including a PhD candidate in their funded personnel
- 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 11 October 2023 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: ILP Scheme Application Remits

The details below are not exhaustive but should serve as a useful guide to applicants in considering relevance and eligibility for this scheme and in selecting the most appropriate remit for their application. Applications will be reviewed upon receipt by HRB staff based on the criteria below. In the case of any queries regarding appropriateness or eligibility, staff will consult with the appointed international Chairs of the relevant Panels before making a final decision.

Patient-Oriented Research (POR)

Patient-oriented research is defined as research conducted with human subjects, or on material of human origin, such as tissues, specimens and cognitive phenomena. The research generally involves patients, samples and/or data from patient and other people who are not patients (e.g. healthy volunteers).

Under the POR remit, the HRB will consider research projects that involve pre-clinical studies, on the understanding that pre-clinical studies represent an important stage of research that occurs before testing in humans to find out if a drug, treatment or procedure is likely to be useful. Such studies gather data on efficacy, feasibility, toxicity, safety, and supports patient eligibility criteria. They typically involve research using particular species of animals and in such cases the HRB will consider supporting animal work. However, appropriate evidence must be provided in the application setting out the case for the pre-clinical study, to justify the choice of species in a manner which resembles the human condition in aetiology, pathophysiology, symptomatology, and response to therapeutic intervention, and describing how the pre-clinical study correlates and aligns with the planned future stages of the research study in humans. In some pre-clinical studies, 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 so alternative *in vitro* pre-clinical studies models can be proposed, but again detailed justification must be provided.

Within POR, **clinical research** is defined as *Research with the goal of improving the diagnosis and treatment of disease and injury and of improving the health and quality of life of individuals as they pass through normal life stages. Clinical research is conducted on or for the treatment of patients and involves direct participation of patients and healthy subjects and/or their samples and/or their data*.

Note: Only applications submitted to the POR panel which begin with research activity to the right of the red line in diagram in Figure 1 will be considered within remit for this panel.

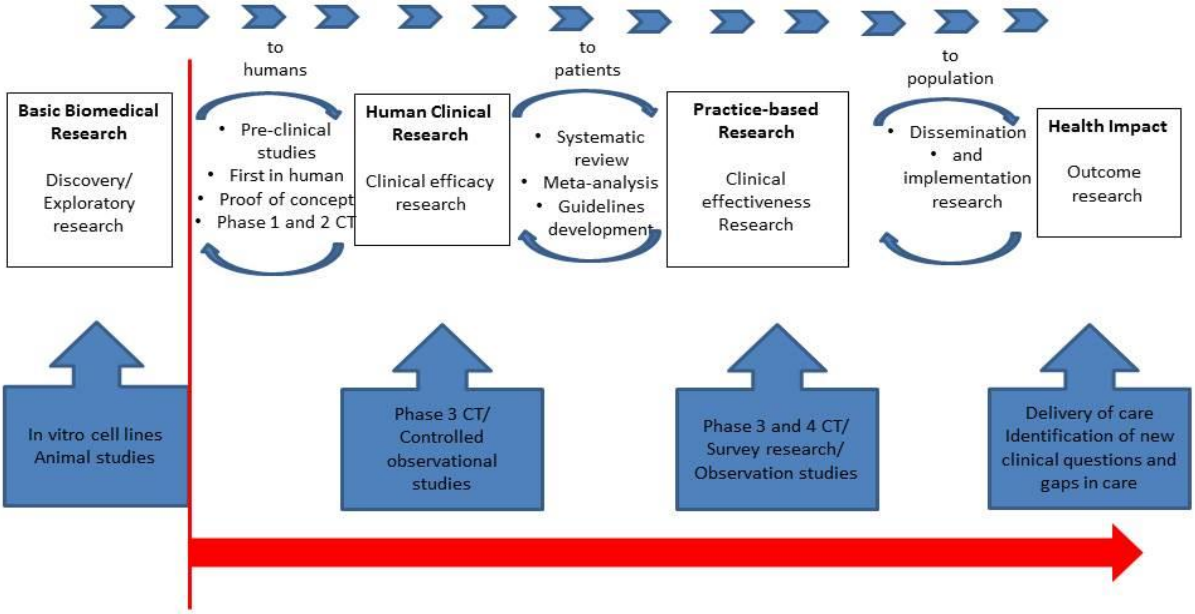

Figure 1 Continuum from research to impacts and outcomes.

Please note that studies aimed at evaluating a full scale, definitive intervention to provide high quality evidence on the efficacy, effectiveness, cost and broad impact of the intervention, and stand-alone **feasibility studies**[21] conducted in preparation for a future definitive intervention are not eligible. Such studies are supported through the HRB Definitive Intervention and Feasibility Awards (DIFA) scheme.

Population Health Research (PHR)

Research with the goal of improving the health of the population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status or through the identification of effective interventions for improving health status and reducing health inequalities.

The emphasis of PHR applications is on prevention of disease, promotion of health and wellbeing and the reduction of inequalities in health. Research focuses on the health of the whole population or on defined sub-groups and aims to generate evidence that is highly relevant to improving the health and wellbeing of the public.

Note: There is significant overlap between clinical medicine and population health approaches. For the purposes of this scheme, if you are submitting a science or medically-driven application where

[21] 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

the emphasis is on disease diagnosis, treatment or care of an individual or a patient group, you should submit your application to the patient-oriented panel.

Applications submitted under the PHR remit should focus on issues such as:

- Macro-level socio-economic determinants of health (the influence of social and economic policies on health)
- Individual-level socio-economic determinants of health (the relationships between access to the resources of society such as housing, income, employment, food security and health)
- Individual behavioural/lifestyle factors such as smoking, nutrition, alcohol and substance abuse, physical activity and sexual behaviour and their impact on health
- Occupational and environmental determinants
- The health of populations over the life course (e.g., birth, child and adult development and ageing)
- Health of specific population groups (e.g., children and youth, people with disabilities, older adults, migrant populations)
- Gender issues and health
- Health protection, promotion, health education and intervention programmes
- Genetic epidemiology
- Prevention and control
- Monitoring and surveillance of population health

Health Services Research (HSR)

Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of healthcare and ultimately health and well-being.

HSR remit includes applications concerning the planning, management, organisation, financing, purchasing and provision of health and social care services. Such research may address aspects of the quality of services, access and equity in provision, relevance and appropriateness to the needs of individuals and communities, effectiveness and efficiency, workforce capacity and capability issues and how services are experienced. Applications focusing on the three main dimensions of quality – patient safety, patient experience and effectiveness of care – are particularly welcome.

Applications focusing on issues such as the following are welcome:

- Access to services
- Strategic management of waiting times
- Health service planning

- Health service delivery and organization
- Integration of care
- Evaluation of health services interventions
- Delivery and organization of hospital and primary health care
- Community-based care (long-term care, home care)
- Chronic disease prevention and management
- Citizen engagement
- Health professional influences on health care
- Public and private health care sectors
- HR and financing of health services
- Health policy and systems management
- Health ethics and law
- Health informatics
- Pharmacoepidemiology
- Quality of life and quality of care
- Health systems and policy

Appendix III: 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[22]. 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.

[22] 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[23] and open publishing directly through the HRB Open Research platform[24]. 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[25] 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.

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

[24] https://hrbopenresearch.org/

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

In line with the HRB's policy on management and sharing of research data[26], all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three 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.

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.

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.

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

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)[27]. 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[28].

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**[29] 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.

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

[28] https://hrcdc.ie/

[29] 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[30] and Retention Policies[31].

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

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

Appendix IV: Resources/Useful Links

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:** 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 SHARNG 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

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/