

# **Applied Programme Grants (APRO) 2023**

**Guidance Notes** 

#### **Guidance Notes**

Key Dates & Times	
Application Open	25 January 2023
Application Closing Date	06 April 2023 @13:00

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

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

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#### 1 Introduction

The Health Research Board (HRB) Strategy (2021-2025)¹ sets out a lead role of the HRB to invest in research that delivers value for health, the health system, society, and the economy. The HRB Strategy aims to invest in research that informs the decisions and actions of knowledge users in the Irish health and social care system by supporting applied research projects. The HRB supports research across the broad range of health and social care through a mix of investigator-initiated and targeted research and across a variety of time horizons. We believe that having knowledge users involved in key stages of the research will lead to improved research outcomes which are more likely to be applied in practice and deliver the greatest benefit.

Programme awards provide support for the long-term development of a health research field by a group of established investigators with an outstanding track record of achievement. Programmes generally comprise a number of high-quality interrelated projects, usually described in separate work packages, that form a coherent theme, where added value is gained from the combination of the various strands of research. Collaboration between research groups and institutions is encouraged. Programme grants focus on specific research objectives that deliver outputs and outcomes that span different aspects needed for a pathway to impact.

The HRB Applied Programme grants (APRO) scheme is a researcher-led scheme aimed at supporting research programmes of up to five years' duration and up to a maximum level of €2.5 million over 5 years. APRO complements other investigator-led research supported through the Investigator-Led Projects (ILP) and applied projects supported through the Applied Partnership Awards (APA). The APRO supports research of a greater scale and ambition compared to these two schemes, aiming to support the area rather than one specific project within the area.

# 2 Aim and Objectives

The APRO aims to support a strategic programme of applied research in health and social care that will have an impact on the health and social care of individuals, population health and the health system in Ireland and beyond.

The objectives are to:

- Address stated national/EU/global priorities in health, public health or social care under the broad thematic areas listed below.
- Support high-quality and team-based research which is likely to lead to a step change in practice and/or in outcomes to the health system, population health, or to service users and carers.
- Tackle an identified problem from a variety of perspectives with a collaborative, complementary and multidisciplinary approach.
- Use a range of multidisciplinary and methodological approaches.

<sup>&</sup>lt;sup>1</sup> https://www.hrb.ie/strategy-2025/

- Develop collaborations between researchers and knowledge users with a view to making outputs useable for implementation or informing policy and decision making.
- Clearly demonstrate how patients, service users and/or carers have been involved and engaged with the programme.
- Include clear plans for implementation, knowledge mobilisation and dissemination.

# 3 Scope of Call

Applied health and social care research for the purposes of this scheme is defined as research with an emphasis on providing evidence that will impact healthcare policy and practice leading to better health outcomes.

While the call announcement does not specify research topics or disease areas, APRO requires that research proposals are submitted under a high-level thematic area as set out below. Only applications within these thematic areas will be funded in this round. These thematic areas reflect broad health and social care challenges nationally and internationally and include areas that cause significant burden or emerging areas where there is a need for increased capacity and additional long-term commitment of funds. They also reflect the Mission and the current Strategy of the HRB.

#### Applications should be submitted under one of the following thematic areas:

- Health, wellbeing and keeping populations healthy and independent throughout life
- Mental health and/or disability
- Social Care and the future of community care
- Non-communicable diseases
- Resilient and sustainable healthcare systems
- Pandemic preparedness and/or antimicrobial resistance
- Digital health and/or personalised medicine

Research programmes that include work-packages in any area within the HRB remit – patient-oriented research, health services research, population health research - are welcome. Programmes seeking to address the integration of health and social care to improve patient, service user and carer outcomes, and those that include work packages aimed at tackling the social care dimension of healthcare problems, are particularly welcome.

It is expected that diverse methodological approaches are adopted, and work packages aimed at addressing specific methodological issues in health and social care research can be included.

<u>Note</u>: Programme Grants are not intended to support exploratory research with no or limited likelihood of significant benefit to health and social care services users, carers and the wider public throughout the programme.

This scheme will support teams of researchers from a broad range of disciplines to work with knowledge users and PPI contributors on a programme of applied health and social care research.

#### Work programmes must:

- Address research question(s) in the thematic areas above and be explicitly linked to documented evidence needs of knowledge user organisation(s).
- Have a number of related research strands which together constitute a broad and coherent work programme.
- Clearly demonstrate the value which will be gained from the combinations of the various strands of research.
- Clearly demonstrate the potential for influencing policy or practice.

Given the scale and breadth of the APRO, it is expected (but not mandatory) that applications include more than one institution and organisation.

#### This scheme will **not fund**:

- Applications involving basic biomedical research.
- Applications using cell lines, animals or their tissue.
- Programmes which are primarily aimed at addressing a gap in the scientific knowledge base.
   While the research proposed in the APRO will add to the scientific knowledge base, this is not the primary aim.
- Applications which are solely literature reviews, audits, surveys, needs assessments or technology development (although these elements may be part of an integrated research study).
- Applications seeking to evaluate a definitive intervention or a stand-alone feasibility study 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.
- 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.

We expect that evidence supporting the case for the research programme 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 an application is outside the scope of the scheme, the application will be deemed ineligible and will not be accepted for review.

# 4 Funding Available, Duration and Start Date

The APRO 2023 scheme will provide funding for research programmes up to a maximum of €2.5M (inclusive of overheads) per award. Funding will be available for Programmes of between 48 – 60 months. The amount awarded and the length of the funding period will depend on the nature of the proposed work. Programmes using novel designs which facilitate shorter, more efficient programmes with earlier results are welcome. Quality permitting, the HRB anticipates making a minimum of 5 awards.

The award will offer research related costs including salary for research staff, running costs, administrative and programme management costs, FAIR data management costs, equipment and dissemination costs, and overheads contributions. Where required, time or backfill for the contribution of knowledge users and PPI contributors may be charged.

<u>Note</u>: The APRO 2023 award will <u>not</u> fund the salary and related costs of tenured academic staff within research institutions (including buy-out from teaching time etc.).

Co-funding from other sources is welcome but not mandatory. It is not part of the formal assessment criteria.

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.

Programmes should start on or as close as possible to 1 November 2023.

# **5 Eligibility Criteria**

This call is not open to Host Institutions from Northern Ireland.

#### 5.1 Applicant Team

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

The researchers in each team should come from a variety of disciplinary backgrounds. The
inclusion of researchers from relevant disciplines not regularly involved in health research (such
as mathematics, business, social sciences, and others) is particularly welcome.

- Knowledge users **must** be included as part of the applicant team as Co-Applicants or official Collaborators depending on their role within the programme.
- PPI Contributors **should** be included as part of the applicant team as Co-Applicants or official Collaborators as appropriate. See <u>Appendix II</u> regarding the role of PPI Contributor.

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.

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 programme. 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 as official Collaborators.

Co-applicants and collaborators from outside the Republic of Ireland are welcome where their participation clearly adds value to the research programme.

#### 5.1.1 Lead Applicant and Leadership team

#### **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 Republic 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.

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 this event.

#### **Leadership Team**

The Lead Applicant is part of a **Leadership Team**, who jointly and collaboratively will oversee the delivery of the programme. The Leadership Team should include all work package leads and others as appropriate.

The Leadership Team **must** jointly demonstrate:

- Complementarity of disciplines, skills and expertise as relevant to the proposed research programme.
- Strong collaborative and networking expertise.
- Strong track record demonstrated by contribution to knowledge, a broad range of research outputs and expertise in accelerating the transfer and application of research evidence into policy and practice.
- Substantial experience of research management.

The HRB would welcome the inclusion of knowledge users and/or PPI contributors as well as talented early career researchers in the Leadership Team as appropriate and feasible.

HRB is a signatory of <u>DORA</u> (San Francisco Declaration of Research Assessment) and explicitly guides reviewers to assess the track record of lead applicants aligned with DORA principles (<u>HRB</u>-Declaration on Research Assessment).

#### **5.1.2** Co-Applicants

**Co-Applicants** include the members of the Leadership Team and others as justified by their role and contribution to the programme.

Co-Applicants will be asked to select whether they are a **Researcher**, <u>Knowledge User</u> or **PPI** contributor co-applicant for the purpose of the proposed research. Up to a maximum of **15 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. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards their own salary if they are in salaried positions. However, researchers in contract positions/independent investigators, knowledge user and PPI contributor Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to the research for the duration of the award.

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 research programme. 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.

#### 5.1.3 Collaborators

An official 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 <u>must</u> be provided for ALL official collaborators. In addition, each official collaborator <u>must</u> 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 research programme, 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<sup>2</sup>.

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 research programme. 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.

#### 5.1.4 Funded Personnel

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

<sup>&</sup>lt;sup>2</sup> https://www.dataprotection.ie/sites/default/files/uploads/2019-07/190710%20Data%20Protection%20Basics.pdf

Unlike the HRB's career development awards, this scheme is <u>not</u> framed as a training initiative. Where junior personnel registered for a higher degree are proposed to work on the programme, Lead Applicants must carefully consider the complexity, scale, objectives and dependencies of the research and the skills, expertise and experience level required to carry it out, especially if involving one or more PhD student(s). In such instances, Lead Applicants must carefully consider the suitability of such research for PhD students, in terms of delivering a clearly identifiable original research project or the potential difficulties in clustering various pieces of work packages for a PhD thesis. The HRB strongly encourages four-year support for PhD candidates in line with other HRB-funded doctoral training programmes such as SPHeRE<sup>3</sup>, ICAT<sup>4</sup> and Collaborative Doctoral Awards (CDA).

# **6 Programme Governance and Management**

It is expected the applicant team will put appropriate management and governance structures in place to ensure the efficient operation of the collaborative team and the delivery of the main objectives of the research programme.

There is flexibility for the applicant team to propose appropriate management, governance and oversight structures as relevant to the proposed programme. This includes at a minimum:

- A Leadership Team to oversee the delivery of the whole research programme and to optimise
  integration and synergies between and across work packages.
  - This group should comprise the Lead Applicant, work package leaders, and others as appropriate and should convene regularly to discuss the scientific progress of the research programme in addition to financial, ethical and personnel issues. Where the Leadership Team does not include all Co-Applicants, a mechanism to ensure regular integration of these in Leadership Team deliberations should be in place.
- A Scientific Advisory Group should play a pivotal role in enhancing the scientific quality of the
  programme, providing feedback on protocols, emerging findings, publications and reports. They
  should consider any new scientific evidence or information relevant to the programme that
  might have a direct bearing on the future conduct of any of the work-packages and they should
  provide advice on the transferability of the research findings into recommendations for practice.
  - This group should comprise a minimum of three International scientific experts of high repute with experience relevant to the research programme and should meet no less than once per year with the Leadership Team. The applicant team is expected to propose membership of the Scientific Advisory Group in the application.

In addition, the constitution of a **Programme Steering Group** should be considered. The purpose of this group is to create a virtuous cycle of influence making results more sustainable, maximising their impact, optimising investment, improving systems, pooling knowledge to avoid overlap of effort and

<sup>&</sup>lt;sup>3</sup> Structured Population and Health Services Research Education Programme <a href="http://www.sphereprogramme.ie/">http://www.sphereprogramme.ie/</a>

<sup>&</sup>lt;sup>4</sup> Irish Clinical Academic Training Programme <a href="https://icatprogramme.org/">https://icatprogramme.org/</a>

feeding into future policy and practice developments. It can contribute to creating synergy between the research programme and local, regional and national policy.

The Programme Steering Group would comprise key stakeholders and constituents not part of the Leadership Team who can commit to ensuring the ability and time to provide regular and meaningful input into the development and implementation of the programme, and that the programme objectives are broadly understood, and activities and outcomes communicated. Membership of this group should be selected based on the expected results of the programme and the likely beneficiaries of the results and findings. This could include individuals, organisations or other target groups (e.g., policy makers, public sector agencies or bodies, international organisations, professional or practitioner groups, commercial/private sector, charities, NGOs or patient/community representative groups).

#### 7 Host Institution

A HRB Host Institution is a research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all HRB award schemes. The **Host Institution for the award** is normally that of the **Lead Applicant** but it may be another organisation/institution designated by the research team, where it is clearly justified. In order to be eligible to apply for funding, an Institution must be an <u>approved</u> 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<sup>5</sup>. Please note that this call <u>is not</u> open to HIs 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. Where such a person is based in an institution that is not the Host Institution for this award, the letter of support should come from that institution. 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 APRO award as a contract researcher; (ii) has an independent office and research space/facilities for which they are 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.

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.

 $<sup>^{5}\,\</sup>underline{\text{http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/}$ 

# 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) (<a href="https://grants.hrb.ie/">https://grants.hrb.ie/</a>).

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

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

#### 8.2 Review Process

Each application submitted to this scheme will undergo a <u>two-phase review</u> 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 Programme
- Public and Patient Involvement in development of and throughout the research programme
- Research Design inclusion of research participants (where applicable)
- Knowledge Translation and Potential Impact of the Proposed Work

Both peer and public review comments will not include any reference to the reviewer's identity or their submitted scores or rating.

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.

Shortlisted applications will be checked for eligibility by HRB staff members and where an application is deemed to be out of scope the chair of the international grant selection panel will be consulted to confirm the recommendation.

#### Phase 2 - Interviews with International Panel

The Interview Panel will comprise of an independent Chair and approximately 6-7 members. 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, knowledge translation/applied health research, etc.). Panel members have access to the application, peer and public reviews. HRB staff members are present to clarify any procedural aspects for the Chair or Panel members and to take notes for the feedback process.

All short-listed Leadership Teams with eligible applications will be invited to attend an interview. During the interview the Leadership Teams will have the opportunity to address any significant concerns/weaknesses described by reviewers.

At the end of the interview panel meeting, a final score is collectively agreed for each application and then they will be ranked according to score. To prioritise between applications with the same score around the funding cut off in the Panel ranking list, the gender of the Lead Applicant recommended for funding may be considered. This means the under-represented gender within the ranked list will be prioritised.

The recommendations of the Interview 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 applicants 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 conclusion of the review process.

#### 8.3 Assessment Criteria

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

#### 1. Research Programme (35%)

- Important research questions with evidence of need
- Design and methodology appropriate
- Appropriate programme governance and management plan, including risk mitigation
- Have PPI; Equality, Diversity and Inclusion and gender been considered?

#### 2. <u>Impact (30%)</u>

Effective integrated knowledge translation planned throughout

- Likely to lead to a step change in practice and/or in outcomes on an individual, population or health system level
- Plans to measure impact

#### 3. Research Team and Environment (35%)

- Applicant team expertise and relevant experience
- Genuine partnership between researchers and knowledge users
- Necessary and beneficial supports, infrastructure, environment in place

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

# 9 Timeframe

Date	
25 January 2023	Call Opening
06 April 2023 @13:00	Call Closing
April to June 2023	Scientific and public review
July 2023	Shortlisting and eligibility check/Outcome communicated
September 2023	Panel Review Meeting
September 2023	HRB Board Decision
October/November 2023	Budget negotiations and contracting
01 November 2023	Earliest start date

#### 10Contacts

For further information on the APRO 2023 contact:

#### Sónia Pereira, PhD

Project Officer - Investigator-led Grants, Research Careers and Enablers

Research Strategy and Funding

Health Research Board

E. spereira@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 of eligibility and 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: <a href="https://grants.hrb.ie">https://grants.hrb.ie</a>

Please refer to the **GEMS Technical Guidance Note**<sup>6</sup>, 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 coapplicants.

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.

Lead Applicant 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 Applied Programme Grants is as follows:

Lead Applicant Eligibility	
I have read the Guidance Notes for the APRO 2023 call	$\checkmark$
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 application for submission to the HRB through the GEMS system.	<b>✓</b>

# 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 APRO 2023 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:

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 $<sup>{}^6 \, \</sup>underline{https://research.ie/assets/uploads/2020/05/CCGT-Grant-Application-System-Technical-Guidance-Notes.pdf}$ 

# **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 that Host Institutions in Northern Ireland are not eligible for this scheme. 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 <a href="mailto:gemshelp@hrb.ie">gemshelp@hrb.ie</a>.

**Note:** In order to be eligible to apply for funding, an Institution must have been approved as a HRB Host Institution <u>no later than two calendar months</u> before the closing date of a call, only preapproved 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 <u>authorised signatory</u> (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 APRO 2023. The signatory's details are prepopulated 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 Programme Details

#### 1.1 Thematic area

Which of the themes of this call does your application address? If more than one, chose the one where the greatest emphasis lies:

- Health, wellbeing and keeping populations healthy and independent throughout life
- Mental health and disability
- Social Care and the future of community care
- Non-communicable Diseases

- Resilient and sustainable healthcare systems
- Pandemic preparedness and antimicrobial resistance
- Digital health and personalised medicine

#### 1.2 Programme Title

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

# 1.3 Programme Duration and Start Date

Please indicate the expected length of the proposed programme in months (minimum duration of 48 months and maximum duration is 60 months) and the proposed start date. The earliest start date is 01 November 2023; programmes should start as close as possible to that date.

# 1.4 Programme Lay Summary

This lay summary is similar to the Programme 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.

#### 1.5 Programme Abstract

This should be a succinct summary of the proposed programme of research. This structured summary should clearly outline the background to the research, the aims and hypotheses of the programme of research. The objectives 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**.

#### 1.6 Keywords

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

#### 1.7 Research question

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

#### 1.8 Development of the application

The engagement between applicant team members in advance of submitting the application should be described, in particular the engagement between researchers, knowledge users and PPI Coapplicants (where appropriate) to ensure the relevance of the different strands of the research programme for policy and/or practice. The word limit is 300 words.

# 2 Applicant Team

Please briefly describe the expertise of each member and their role in the programme. The word limit is **250** words for lead applicant and co-applicants and **100** words for collaborators.

Please briefly describe how the disciplinary, professional and experiential expertise described above maps onto the expertise required throughout all aspects of the programmes. The word limit is **300** words.

# **3 Programme 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 Programme Description must include:

- Current Knowledge, Background to the Area, Relevance and Knowledge Gap
- Overall Aim
- Research Programme (plus Gantt chart or alternative)
- Research Design and Methodological Approach
- Knowledge Translation Plan
- Impact Statement
- IP Considerations
- Programme Governance and Management
- FAIR Data Management and Stewardship
- Public, Patient and Carer Involvement (PPI) in the Research Programme
- Gender and/or Sex Issues in the Research Programme

- Potential Safety Risks and Ethical Concerns
- Biobanking (where appropriate)
- Programme Description Figures
- References

# 3.1 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 programme of research 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 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**.

<u>Note</u>: you are strongly advised to read the Guidance Notes and in particular the assessment criteria when writing this section.

#### 3.2 Overall Aim

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

#### 3.3 Research Programme

Please outline the proposed research programme including each work package. Please indicate how they integrate to form a coherent programme of research. Each work package should include objectives and a subset of deliverables which will be finalised during contract negotiations as informed by the international review panel.

Work packages should be mapped against estimated completion timelines in a **Gantt chart**, and any milestones highlighted.

The word limit is 2000 words.

## 3.4 Research Design and Methodological Approach

Summarise the research design and methodological approach for each, individual work packages.

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 questions.

#### 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 must be described and justified, and aligned with the study aim, objectives and goals and the context of the study.

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

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

Useful links and resources are summarised in Appendix III.

#### 3.5 Knowledge Translation Plan

The application should include a clear and concise knowledge translation plan that will highlight how the researchers, knowledge users and other relevant stakeholders will engage throughout the lifetime of the programme to ensure that findings will be applied by the knowledge user organisation/s, and others as appropriate (integrated Knowledge Translation – iKT)<sup>7</sup>.

Please outline the knowledge translation plan including the processes or steps that will be undertaken on an ongoing basis to ensure that emerging findings, or changes in the external environment, can help shape and refine the plan and support the uptake of research findings to influence health and social care policy and/or practice. It should describe the management process

<sup>&</sup>lt;sup>7</sup> Guide to knowledge translation planning at CIHR: integrated and end of grant approaches [http://www.cihr-irsc.gc.ca/e/45321.html]

that will be used to ensure that the knowledge from the research is not just shared but is actively translated and/or refined further.

While the emphasis of this section is on iKT, you should also consider knowledge translation more generally.

Describe how the research outputs you anticipate producing during and after this programme will be disseminated and shared and made openly accessible, in line with HRB Open Access Policy<sup>8</sup>. 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<sup>9</sup>.

Applicants are advised to consider the following:

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

Types of publication routes include 10:

**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/).

<u>Note</u>: applicants are strongly advised to read the Guidance Notes and in particular the assessment criteria that will be used to assess applications. The word limit is <u>300 words</u>.

<sup>&</sup>lt;sup>8</sup> https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/open-access/

<sup>&</sup>lt;sup>9</sup> All HRB Host Institutions must subscribe to the National Intellectual Property Protocol, 'Inspiring Partnership- the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland', prepared by Government/Knowledge Transfer Ireland to ensure transparent and consistent procedures for managing Intellectual Property from publicly funded research.

<sup>&</sup>lt;sup>10</sup> https://www.jisc.ac.uk/guides/an-introduction-to-open-access

#### 3.6 Impact Statement

Describe the anticipated outputs and outcomes of the proposed research. Please provide details on the likely impact of this research on human health and wellbeing indicating the anticipated timescale for any proposed benefits to be realised. Please consider areas for impact such as, but not limited to, providing the basis for new/improved healthcare innovations, influencing policy and practice, increasing enterprise activity. Outline what steps are necessary for these impacts to be realised, and criteria for how to measure the success of the programme.

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 <u>400 words</u>.

#### 3.7 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<sup>11</sup>. 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**.

#### 3.8 Programme Governance and Management

It is expected that Applicant team will put appropriate management and governance structures in place to ensure the efficient operation of the collaborative team and the delivery of the main objectives of the programme.

There is flexibility for the applicant team to propose appropriate management, governance and oversight structures as relevant to the proposed programme. However, the HRB expects a Leadership Team and international Scientific Advisory Group to be set up at a minimum.

Please describe:

The Leadership Team

<sup>&</sup>lt;sup>11</sup> National Intellectual Property Protocol, 'Inspiring Partnership- the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland'

- The Scientific Advisory Committee
- Any other oversight, advisory or governance structures that are crucial to the delivery of the programme for example a Programme Steering Group.
- Outline the processes that will be put in place to ensure that the programme is well managed and administered, commenting on the programme management, meetings schedules, financial management etc.
- Please name the members of these structures wherever possible.
- Describe contingency plans, including how you intend to manage any risks to the delivery of the programme.

The word limit is **800 words**.

Please include an image of the proposed **governance model** as a file upload here.

# 3.9 FAIR Data Management and Stewardship

Describe the general approach to data management and stewardship that will be taken during and after the Programme, 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 reused during the research programme.

Please consider the FAIR Guiding Principles for scientific data management and stewardship: Findability, Accessibility, Interoperability, and Reusability<sup>12</sup>.

- 1. <u>Data description and collection or reuse of existing data</u>: (a) What is the type, format and volume of data? (b) How will the data be collected, created or reused?
- 2. <u>Documentation and data quality</u>: (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. <u>Data sharing and long-term preservation:</u> (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

<sup>12</sup> 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).

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. <u>Data management responsibilities and resources:</u> (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.

### 3.10 Public, Patient and Carer Involvement (PPI) in the Research Programme

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 <u>Appendix III</u>. Please be aware there are PPI Ignite Network offices in some host institutions.

Are you including PPI in your application?

#### If Yes

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

- Identifying and prioritising the programme of research
- Design
- Conduct
- Analysis
- Oversight
- Knowledge Translation

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, patients or carers are involved, they should be compensated for their time and contributions; this should be reflected in the programme 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 programme.

The word limit is 600 words.

# 3.11 Gender and/or Sex Issues in the Research Programme

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 programme.

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

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

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

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

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

The word limit is 200 words.

# 3.12 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 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 **200 words**.

#### 3.13 Biobanking

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

If yes, please describe how biobanking within this programme 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. In this form, please describe how you will ensure good practice for biobanking components in this programme, 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<sup>13</sup>. Some useful links are in <u>Appendix III</u>. The word limit is <u>300 words</u>.

# 3.14 Programme Description Figures

Two file upload option is available to include an attachment to support your Programme Description. Two documents, with a <u>maximum of 5 figures each</u> (can be a combination of images, graphs, tables, scales, instruments, or surveys), may be uploaded as two individual documents on HRB GEMS. Additional references should not be included here. They must <u>not</u> be embedded within the text of the Programme Description. The maximum size is <u>2MB</u>. Files should be doc, docx, or pdf.

#### 3.15 References

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

#### 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

# **4** Infrastructure and Support

#### 4.1 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 **300 words**.

<sup>13</sup> https://search.coe.int/cm/Pages/result\_details.aspx?ObjectId=090000168064e8ff

#### 4.2 Access to Research Infrastructures

Applications availing of the advice, research design, data management services and/or other forms of support from a longitudinal study or other data set, 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) 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.

# **5 Programme Budget**

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

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

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

#### The total funding available will be up to €2.5M over 48-60 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 <a href="http://www.iua.ie/research-innovation/researcher-salary-scales/">http://www.iua.ie/research-innovation/researcher-salary-scales/</a> .

	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, employer's PRSI contribution, and overhead contribution) in the budget.  Salaried researchers who are registered for a PhD degree (e.g., clinical fellows) 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.  In line with the proposed new pay agreement for State employees please apply a salary contingency of 3% from 1st October 2024 onwards. Please note this contingency should be applied cumulatively year on year.  Note: The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits.
b) Employer's PRSI	The HRB does not provide salary or buy out time for collaborators  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). The level of employer contribution should be in accordance with the model adopted by the Host Institution.  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	The HRB student stipend is €19,000 per annum (tax exempt).
e) Student Fees	Fees for students registered for a higher degree at EU level only. Applicants should liaise with their Host Institution's Research Office for fee levels. <b>Annual increments are not provided within budget</b> .
2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs etc.  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'.  Costs associated with compensating Knowledge users and PPI contributors involved in your research e.g., consultation workshops, time spent reviewing material, costs of participation in advisory groups, travel expenses, payments for time (in line with your Host institutions policies), etc. should be charged to running costs.  The following costs are ineligible and will not be funded: training courses/workshops with the exception of training in public and patient involvement in research, inflationary increases, cost of electronic journals.)  Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.

3. 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 research programme 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.
4. 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 exchange plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research <sup>14</sup> . 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.
5. 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 <b>incurred during the lifetime of the programme</b> . Please see table below for further guidance.
6. Administration costs	Any costs associated with the management of a Programme.
7. Overhead Contribution	In accordance with the HRB Policy on Overhead Usage <sup>15</sup> , 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 <b>laboratory or clinically based research</b> and 25% of Total Direct Modified Costs for <b>desk-based research</b> .  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.

# **5.1** 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	Secondary data access, costs for preparing data for sharing (e.g., anonymisation)
	Costs for depositing research data and metadata in an open access data repository
Deposition and reuse	Defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please further explain

 $<sup>^{14}\,\</sup>underline{\text{http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/}$ 

 $<sup>^{15}\,\</sup>underline{\text{http://www.hrb.ie/funding/schemes/before-you-apply/all-grant-policies/hrb-policy-on-usage-of-research-overheads/}$ 

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

#### 5.2 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.

# 5.3 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.

# 6 Ethical Approval

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 <u>only</u>). 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.

# 7 Applicant Team Details

#### 7.1 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.

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 <u>are automatically included in any application created involving that individual.</u> You are asked to select your 5 most relevant publications for this application.

Note: The HRB is 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 <a href="https://orcid.org/">https://orcid.org/</a>.

#### **Publications and Funding Record**

You are asked to include your 5 most relevant publications to this application.

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.

#### **Evidence of Relevant Leadership Experience**

The Lead Applicant is asked to describe any evidence of expertise or experience that they have in leading consortia of different stakeholders and perspectives, this does not need to be a research consortium. The word limit for this is **200 words**.

#### Additional evidence of experience and expertise relevant to this application

The Lead Applicant can describe any additional experience or expertise that provides evidence of their ability to successfully lead the proposed programme. Knowledge translation activities that relate to the work described in your application. This may include for example communication & dissemination (beyond publications), development of IP (patents, licenses), development of guidelines and standards, knowledge exchange and outreach activities. If planning to supervise a student, information regarding supervisory experience must be included. Please use this opportunity to describe any career gaps in your CV. The word limit is **200 words**.

# 7.2 Co-Applicant Details

The Lead Applicant can add <u>up to 15 Co-Applicants</u> 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 override 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.

#### 7.2.1 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

Each Researcher Co-Applicant will be asked to describe any additional experience or expertise that will provide evidence of their ability to successfully lead the proposed programme. Knowledge translation activities that best relate to the work described in your application. This may include for example communication & dissemination (beyond publications), development of IP (patents, licenses), development of guidelines and standards, knowledge exchange and outreach activities. If planning to supervise a student, information regarding supervisory experience must be included. Please use this opportunity to describe any career gaps in your CV. The word limit is **200 words**.

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

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 - 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 are fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team.

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

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

#### 7.2.2 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 programme. The word limit is <u>300 words</u>.

**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 Patient Public Involvement in their knowledge user role, and roles/responsibilities as a constructive and effective change agent. The word limit is **200 words**.

#### 7.2.3 PPI Contributor Co-Applicants

**PPI Co-Applicants** should provide 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**.

#### 7.3 Collaborator Details

The Lead Applicant can add <u>up to 10 collaborators</u> per application. Unlike Co-Applicants, the information for Collaborators <u>is not</u> 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.

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.

# **Submission of Applications**

The deadline for submission of complete applications is 06 April 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 <u>upload</u> 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 <a href="https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-appeals/">https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-appeals/</a>

# **Appendix II: HRB Funding Policies and Procedures**

#### Access and support from research infrastructures

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

An Infrastructure Agreement form will be requested as part of the application addressing the nature/scope of the service or collaboration, the rationale behind the choice of facility/centre/network and any costs associated with the programme (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, Patient and Carer Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public, patients and carers in the research that we fund<sup>16</sup>. 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/carers as participants in research.

PPI represents an active partnership between members of the public, patients and carers 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 programme 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.

<sup>16</sup> 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, patients or carers 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 and open publishing directly through the HRB Open Research platform 18. The HRB is driving the making of research data FAIR (Findable, Accessible, Interoperable and Re-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles<sup>19</sup> provide a guideline for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals. For researchers, the move to FAIR and open data, where applicable, means researchers should consider data management issues and find suitable data repositories at the research planning stage.

Applicants will have to provide information about their plans for data management and data sharing at application stage.

In line with the HRB's policy on management and sharing of research data<sup>20</sup>, all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three

<sup>&</sup>lt;sup>17</sup> http://www.hrb.ie/funding/policies-and-principles/open-research/

<sup>18</sup> https://hrbopenresearch.org/

<sup>19</sup> https://www.nature.com/articles/sdata201618

<sup>&</sup>lt;sup>20</sup> https://www.hrb.ie/fileadmin/user\_upload/HRB\_Policy\_on\_sharing\_of\_research\_data.pdf

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

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

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.

#### **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)<sup>21</sup>. 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<sup>22</sup>.

#### **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**<sup>23</sup> 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 <u>under-represented gender</u> 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.

# **Appeals procedure**

<sup>&</sup>lt;sup>21</sup> http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

<sup>22</sup> https://hrcdc.ie/

<sup>&</sup>lt;sup>23</sup> http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-gender-in-research-funding/

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

# **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<sup>24</sup> and Retention Policies<sup>25</sup>.

<sup>24</sup> https://www.hrb.ie/about/legal/privacy-policy/

<sup>&</sup>lt;sup>25</sup> https://www.hrb.ie/fileadmin/user\_upload/HRB\_Document\_retention\_policy..docx

# **Appendix III: Resources/Useful Links**

#### **REPORTING**

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

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

**Registry of Research Data Repositories** 

http://www.re3data.org/

Zenodo Data Repository (OpenAIR)

https://zenodo.org/about

https://zenodo.org/

#### **EVIDENCE SYNTHESIS**

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

https://evidencesynthesisireland.ie/

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

www.thecochranelibrary.com

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

https://www.campbellcollaboration.org/

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

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

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

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

#### **CLINICAL RESEARCH INFRASTRUCTURES**

All Ireland Hub for Trials Methodology Research

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

Centre for Advanced Medical Imaging, St James' Hospital Dublin

http://www.3tcentre.com/

Centre for Support and training Analysis and Research (CSTAR)

http://www.cstar.ie

**Children's Clinical Research Unit** 

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

**Clinical Research Support Unit, Limerick** 

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

Clinical Research Centre, Royal College of Surgeons in Ireland

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

**Clinical Research Facility, University College Dublin** 

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

**Clinical Research Support Centre (Northern Ireland)** 

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

HRB Clinical Research Facility, Cork (HRB CRFC)

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

HRB Clinical Research Facility, Galway (HRB CRFG)

http://www.nuigalway.ie/hrb\_crfg/

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

ICC-CTN (iccctn.org)

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

In4kids

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

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

**HRB Trials Methodology Research Network (TMRN)** 

http://www.hrb-tmrn.ie

The National Clinical Trials Office (NCTO)

Email trials-ireland@ucc.ie

https://ncto.ie/

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

http://www.sjhcrf.ie/

#### **BIOBANKING**

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

https://search.coe.int/cm/Pages/result\_details.aspx?ObjectId=090000168064e8ff

BBMRI-ERIC is a European research infrastructure for biobanking

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

**OECD Guidelines on Human Biobanks and Genetic Research Databases** 

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

**ISBER Best Practices for Repositories** 

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

**Molecular Medicine Ireland Biobanking Guidelines** 

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

NCI Best Practices for Biospecimen Resources (2016 version)

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

# PUBLIC, PATIENT AND CARER INVOLVEMENT IN RESEARCH & RESEARCH PRIORITIES

The National PPI Ignite Network <a href="https://ppinetwork.ie/">https://ppinetwork.ie/</a>

**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

#### **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

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

#### **IMPLEMENTATION SCIENCE RESOURCES**

#### **Centre for Effective Services**

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

#### **UCC Implementation Science Training Institute**

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

#### **European Implementation Collaborative**

https://implementation.eu/resources/

#### **CO-CREATION RESOURCES**

#### **ACCOMPLISSH Guide to impact planning**

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

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

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

#### **INFORMATION ON PERSISTENT IDENTIFIERS**

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

http://www.doi.org/registration\_agencies.html

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

http://www.handle.net/

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

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

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

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

#### **DATA REPOSITORIES**

**Registry of Research Data Repositories** 

http://www.re3data.org/

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

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

Zenodo Data Repository (OpenAIR)

https://zenodo.org/

# **FAIR/OTHER USEFUL LINKS**

**Main FAIR Principles** 

https://www.go-fair.org/fair-principles/

**UK Concordat on Open Research Data (July 2016)** 

http://www.rcuk.ac.uk/documents/documents/concordatopenresearchdata-pdf/

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

https://creativecommons.org/choose/