HRCI-HRB Joint Funding Scheme 2024

Guidance Notes for Applicants

Guidance Notes

Key Dates & Times	
Charities Open Calls	June 2023 onwards
Charities Internal Application Deadline	October 2023
HRB Application Deadline	27 March 2024 @13:00

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1 Introduction

The HRB is the lead agency in Ireland supporting research linked to health and social care. During the period of the Strategic Business Plan 2021-2025, the HRB will continue to work in partnership with others to fund strategically relevant health research projects to to create new knowledge that, over time, will help to address major health challenges in society and have an impact on tomorrow's healthcare.

Health Research Charities Ireland (HRCI) is the national umbrella organisation of charities active in health and medical research, together representing over 1 million Irish patients. Their approximately 40 members span very diverse areas of health, including rare diseases, cancer, childhood illnesses, dementia, mental health, and many forms of chronic illness and disability. Through support and advocacy, they represent the joint interests of their members, working with them and the wider health research community to improve health and prevent illness through research.

HRCI's members have an important role in health research. In addition to providing funding, they increase the quality and quantity of research in a myriad of ways, including through ensuring its relevance to patients, hosting research conferences, supporting research infrastructure such as patient registries, helping to ensure patient impact from research and communicating research developments to the public.

Since 2006, the work of HRCI and its members has been supported by the Health Research Board (HRB) through co-funding of research projects. The level of funding is currently at €1,000,000 per annum.

This innovative joint funding scheme allows members of HRCI to support research addressing their research strategy, where they might otherwise not be in a position to finance the full cost of that research. To date, 153 projects have been jointly funded by member charities and the HRB in eleven rounds. While no differentiation is made between charities or disease areas, the scheme has been particularly beneficial for rare diseases where research being undertaken internationally may be limited and where charities wishing to contribute to the research agenda need to fund research projects led from outside Ireland.

HRCI and HRB have developed guidelines for competitive peer review to ensure that high quality and innovative research projects receive funding through this scheme. The partnership with the HRB supports the building of research funding capacity in Irish research charities and ensures that all elements of this research funding programme are operated at the highest standards of best international practices.

The HRCI member charities and the HRB are now inviting applications for its 2024 call of the HRCI-HRB Joint Funding Scheme.

2 Aim and Objectives

HRCI/HRB Joint Funding Scheme aims to fund researchers and research teams to conduct internationally competitive and innovative research in **areas of strategic relevance to each individual charity**.

The objectives are to:

- Fund research that addresses the strategic aims of the individual charities
- Support high quality, internationally relevant research
- Create new knowledge and evidence of benefit to health and social care

3 Scope of Call

This scheme provides funding for clearly defined research projects in areas of strategic relevance to each individual charity. It allows for co-funding of a single project by either up to four Irish HRCI charities or by one Irish HRCI charity and an international charity.

We expect that evidence supporting the case for the project has been gathered systematically, i.e., as systematic reviews or other evidence synthesis formats. Simple literature overviews are not sufficient. Evidence synthesised systematically should include evidence of (1) a systematic identification of previous work, (2) critical appraisal, (3) synthesis of the evidence and (4) interpretation of findings.

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

- Applications planning to include PhD candidates.
- Applications which are solely literature reviews, audits, surveys, needs assessments or technology development (although these elements may be part of an integrated research study)
- Studies aimed at evaluating a full scale, definitive intervention to provide evidence on the efficacy, effectiveness, cost and broad impact of the intervention, and stand-alone feasibility studies[1] conducted in preparation for a future 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

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

- Applications which are solely **or** predominately health service developments or implementation of an intervention without a predominant research element. The HRB will not fund the cost of providing the service or intervention 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

Where an application is outside the scope of the scheme, the application may be deemed ineligible by the review panel.

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

4 Funding Available, Duration and Start Date

The HRCI-HRB Joint Funding scheme will provide funding for projects up to a maximum of **€300,000** (**exclusive** of overheads) per award. The award will offer research related costs including salary for research staff, running costs, PPI costs, FAIR data management costs, equipment and dissemination costs, and overheads contributions. Overheads of 30% of Total Direct Modifiable Costs will be added to the portion of the research funded by the HRB (see Appendix I section 5.2 Overheads Contribution).

A total commitment in the region of 3.1M (HRB contribution of €1.75M and charities contribution of €1.35M) will be made. Quality permitting it is expected that a minimum of 11 awards will be funded. Awards will have a duration of between **12 and 36 months**.

Note: The HRCI-HRB Joint Funding Scheme will not fund the salary and related costs of tenured academic staff within research institutions (including buy-out from teaching time etc.).

The budget requested and the award duration **must** reflect the scale and nature of the proposed research, and reviewers will thoroughly assess the level of funds and timeframe requested when reviewing the application.

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

5 Eligibility Criteria

This call **is** open for Host Institutions from Northern Ireland and other non-Republic of Ireland Host Institutions.

Funding outside the island of Ireland **is allowable** where there is no established research capacity in Ireland (e.g. for the case of rare diseases).

Non-Republic of Ireland Host Institutions will be required to sign up to the HRB's Terms & Conditions.

The Joint Funding Scheme allows for co-funding of a single project by either up to four Irish HRCI charities or by one Irish HRCI charity and an international charity.

5.1 Applicant Team

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

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

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

A **knowledge user** is defined as one in a position of authority to influence and/or make decisions about health policy or the delivery of services and can act to ensure that the findings of the research will be translated to influence decision making and change within their (or other) organisations. This is typically a health-system manager, policy maker, health professional or clinician who is in a position to make significant changes to policy or practice. Knowledge user organisations may be Government departments, agencies, hospitals, 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.

5.1.1 Lead Applicant

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

The Lead Applicant **must**:

- Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland or in their non-Republic of Ireland Host Institution (the "Host Institution") as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable. **OR**
- Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

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

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

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

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

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

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

Where the PI is based outside the island of Ireland, where possible they should seek Co-applicants or Collaborators in Ireland in order to build capacity here.

As signatory of the DORA Declaration[2], the HRB is committed to supporting a research environment where importance is placed on the intrinsic value and relevance of research and its potential impact in society (HRB - Declaration on Research Assessment).

5.1.2 Co-Applicants

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

A Co-Applicant has a well-defined, critical, and substantial role in the conduct and steering of the proposed research. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards their own salary if they are in salaried positions. However, researchers in contract positions/independent investigators, knowledge user and PPI contributor Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to the research for the duration of the award. (**up to a maximum of 6 Co-Applicants can be listed).**

The terms of any co-application should be determined early, and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up co-application agreements.

5.1.3 Collaborators

A Collaborator is an individual or an organisation who will have an integral and discrete role in the proposed research and is eligible to request funding from the award when properly justified. Named collaborators may include investigators or organisations from outside the Republic of Ireland, but an individual or organisation should **only** be named as Collaborator if they are providing specific contributions (either direct or indirect) to the activities. A collaborator may provide training, supply samples or kits, provide access to specific equipment, specialist staff time, staff placements, access to data and/or patients, instruments or protocols, industry know-how, or may act in an advisory capacity. Collaborators can come from a range of backgrounds such as academia, the private sector, a healthcare organisation, the charity sector, or a patient group (**up to a maximum of 10 Collaborators can be listed)**.

Profile details **must** be provided for ALL collaborators. In addition, each collaborator **must** complete a **Collaboration Agreement Form**. A template Collaborator Agreement form will be provided along with all other documents in the application pack.

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)

[2] Home | DORA (sfdora.org)

are an integral part of the proposed project, evidence of commitment and access must be demonstrated by having the Data Controller or key Gatekeeper of a study included as a Collaborator.

A 'Data controller' refers to a person, company, or other body that decides how and why a data subject's personal data are processed. If two or more persons or entities decide how and why personal data are processed, they may be 'joint controllers', and they would both share responsibility for the data processing obligations[3].

The applicant team will be asked to describe any relevant agreements that they have entered into to facilitate their partnership working. The terms of any collaboration should be determined early, and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, ownership and copyright, access and sharing of data and samples etc. when working up Partnership proposals.

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 project and that they possess the necessary breadth and skills in all methodological areas required to deliver the proposed programme of work. Alignment between personnel requested and the proposed project should be demonstrated. Roles and responsibilities of funded personnel must be differentiated and clear.

This scheme is not framed as a training initiative for PhD candidates and HRB expects PhD programmes to run for four years. Where candidates for a Master's degree are proposed to work on projects, Lead Applicants must carefully consider:

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

If proposing a Master's candidate, please note the following:

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

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

6 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 approved HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for research performing organisations to be approved as HRB Host Institutions can be found on the HRB website[4].

Host Institutions outside of the Republic of Ireland are not required to be approved as HRB Host Institutions but must sign up to the HRB'S Terms & Conditions.

Host Institution Letters of Support must be provided for **(1) all Lead Applicants in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary.** The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*Host Institution - insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB HRCI-HRB JFS 2024 award as a contract researcher; (ii) has an independent office and research space/facilities for which they is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team. Electronic signatures are acceptable.

It is the responsibility of the Charity, with input from 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.

7 Application, Review Process and Assessment Criteria

7.1 Application

All applications must be made to the HRCI-registered research charity on or before their own set closing dates. The application documents will be provided for you by the charity. All application documents must be completed in font Calibri Size 11. It is the responsibility of the Lead Applicant to

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

ensure that applications are completed in full, and all the necessary documentation is received by the charity on or before the closing dates indicated.

7.2 Review Process

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.

Each eligible application submitted to this scheme will undergo a two-phase review process.

Phase 1 is managed by the relevant co-funding Charity and Phase 2 is managed by the HRB.

Phase 1 (Charity)– International Peer Review, and Shortlisting

For this scheme the International Peer Review process is managed by the relevant co-funding Charity using guidance provided by the HRB. The HRB Conflict of Interest Policy is applicable.

For each application, the charity aims to receive written feedback from at least three international peer 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 charity, the HRB and to panel members.

Short-Listing by HRCI-registered Charity

Each charity will conduct an internal selection process. Whilst individual charities may have additional criteria, the **relevance of the application in addressing the strategic aims of the charity** will be a core criterion. Charities will also provide details of their PPI review process where used and how this informed their application selection panel. The charities' justification for selection of applications and their strategic plan will be forwarded alongside the nominated applications to a HRCI-HRB-jointly nominated selection Panel.

Applicant Response

Applicant teams of shortlisted applications will be provided with a time-limited opportunity to respond to peer review comments (see Section 8 Timeframe).

Once notified that the application is short-listed by the charity; the peer review comments will be made available to the Lead Applicant. The Lead Applicant will have 10 working days only to submit their response to the Charity, and the response has a **maximum word count of 2000 words only for the peer review response** (including references). No figures can be uploaded. The response can be used by the Charity Selection Panel to inform their process and will be provided to members of the Review Panel, in advance of the Panel meeting, along with the application, the peer review comments and rating.

Grant E-Management System (GEMS)

Short-listed applications will be submitted to the HRB through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie/) by the co-funding Charity. **The co-funding Charity is responsible for the creation of the application and submission at this stage.**

Phase 2 (HRB) - Panel Review (Public and Scientific)

Applications will be initially checked for eligibility by HRB staff members.

An international grant selection committee will be convened consisting of both Scientific and Public panel members. Scientific panel members are selected based on the range of applications received and the expertise and skillset needed (e.g., research area and methodological and analytical approaches, coaching and mentoring, knowledge translation/applied health research, etc.). Panel members are assigned as lead and secondary reviewers to specific applications. Public panel members are selected from suggestions made by Charities and the HRB database of public reviewers.

This panel will have access to the original applications, charity background information on work and strategic research priorities, international peer reviewer comments, applicant's response to reviewers' comments and the charities' endorsement.

HRB and HRCI staff members are present at the meeting to clarify any procedural aspects for the Chair or Panel members and to take notes for the feedback process. Charities representatives are invited to observe the meeting.

Scientific panel members will review the strengths and weaknesses of the application on the stated assessment criteria for the call (Section 7.3 Assessment Criteria) and will provide comments as well as **a score**. PPI panel members will only assess the quality of PPI in the application. They will review each application, provide comments, and assign **a rating** according to the appropriate level of PPI for the proposed research. A table detailing the ratings, their associated descriptors and scores can be found in Appendix IV.

The PPI rating will be used to adjust the consensus scientific score, by applying a correction to it.

PPI Panel Members are asked to comment on the following:

- The Plain English Summary (Lay Summary)
- Relevance of the Proposed Research Question
- PPI in development of and throughout the project
- Making it straightforward for research participants
- Dissemination of the Proposed Work

Their PPI rating will inform the consensus Panel score, and therefore the final ranking and recommendation for funding.

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

The Scientific panel members will review the strengths and weaknesses of the application relating to the assessment criteria detailed below. Successful applicants are expected to score well in all review criteria.

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

The recommendations of the Review Panel will be presented for approval at the next scheduled HRB Board meeting. When the Board of the HRB has approved the process and recommendations, HRB staff will contact the Lead Applicants, the co-funding charities, and Host Institutions to notify them of the outcome. A summary of Panel Member's comments and the panel discussion comments will be issued to the Lead Applicant following the Board approval stage.

7.3 Assessment Criteria

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

Scientific Quality and Innovation (50%)

- Important research question (panel review stage only)
- Evidence supports need for proposed project
- Design and methodology appropriate
- Project plan and risk mitigation for project delivery

Research Team and Environment (30%)

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

Impact (20%)

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

Applicants need to score well across these criteria to be successful. An assessment of your PPI approach will influence the assessment of these criteria.

8 Timeframe

Date	
06 September 2023	HRB Call Opening
June 2023 onwards	Charity Calls Open
October 2023 - January 2024	Peer review period
January - February 2024	Applicant response
February - March 2023	Charity Selection Panels
May 2024	Joint Panel Review Meeting
June 2024	HRB Board Decision
July-September 2024	Budget negotiations and contracting
01 October 2024	Earliest start date

9 Contacts

For further information on the HRCI-HRB Joint Funding Scheme, contact:

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HRCI

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Project Officer

Research Strategy and Funding

Health Research Board

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

Appendix I: Detailed Guidance on the Application Form

Applicants will be required to complete their applicant using the application form (Form B1) and associated documents provided in the **application pack**. This will be provided to each co-funding Charity by HRCI in advance of the call opening.

Applicants are responsible for the completion of their own application and for its submission to the respective charity in accordance with that **charity's deadline.**

If an application is shortlisted by the Charity (through their selection process) then the charity will become responsible for the upload and submission of this application to the HRB. This will be completed via GEMS and will consist of all of the documents in the application pack in addition to a charity information form.

The following details are captured in the application form (**Form B1**):

Project Title

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

1 Details of Lead and Co-Applicants

1.1 Lead Applicant's Details

Details are requested about the **Lead Applicant** including their title/position and contact details.

1.2 Co-Applicants' Details

Details are requested about the **Co-Applicants** including their title/position and contact details. The Lead Applicant can add up to 6 Co-Applicants to an application.

1.3 Host Institution

For the purposes of contracting, payment, and management of the award, HRB funds can only be awarded to HRB approved Host Institutions, including those in Northern Ireland. Please note this call is open to non-island of Ireland Host Institutions. 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.

Please list the Host Institution for this award**, i.e. the institution to which the research award will be made.** Provide details of the Dean of Research/CEO/equivalent authorised person of that institution.

A list of island of Ireland Host Institution, recognised by the HRB at the time of this call going live can be found on this list.

Note: For island of Ireland Host Institutions, to be eligible to apply for funding, an Institution must have been approved as a HRB Host Institution no later than two calendar months before the closing date of a call, only pre-approved Host Institutions will appear on the list linked above. Host Institutions outside of the island of Ireland do not need to be approved but must be prepared to sign up to HRB Terms & Conditions.

2 Project Description

2.1 Project Lay Summary

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

2.2 Project Abstract

This should be a succinct summary of the proposed research. This structured summary should clearly outline the background to the research, the aims and hypotheses of the project. The objectives of the project and what the work is expected to establish should be described. It provides a clear synopsis of your application and should set the research application in context. The word limit is **300 words**.

2.3 Relevance of research to strategic aims of the charity or charities

Please set out the relevance of your application in addressing the strategic aims of the charity or charities (in the case that two charities are co-funding) and why the charity/charities should select your application to bring forward to the HRCI/HRB-jointly nominated selection panel. Where available, refer specifically to the strategic plan of the charity/charities you apply to, and to any other relevant strategy documents. The word limit is **300 words**.

2.4 Keywords

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

2.5 Project Description

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

The Project Description must include:

- Research Question
- Current Knowledge, Background to the Area, Relevance and Knowledge Gap
- Overall Aim
- Objectives and Deliverables (plus Gantt chart or alternative)
- Research Design and Methodological Approach
- Impact Statement
- IP Considerations
- Dissemination and Knowledge Translation Plan
- Project Management
- FAIR Data Management and Stewardship
- Public and Patient Involvement (PPI) in the Research Project
- Gender and/or Sex Issues in the Research Project
- Potential Safety Risks and Ethical Concerns
- Biobanking (where appropriate)
- Project Description Figures (where appropriate)
- References

2.5.1 Research Question

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

2.5.2 Current Knowledge, Background to the Area, Relevance and Knowledge Gap

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

interpretation of findings. Where available, include a description of any pilot work, professional and consumer consensus studies already undertaken.

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

2.5.3 Overall Aim

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

2.5.3.1 Objectives and Deliverables

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

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

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

2.5.4 Research Design and Methodological Approach

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

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

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

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

If your project involves the use of animals, provide sound scientific justification for their use, explain why there are no realistic alternatives, and demonstrate that the numbers proposed will allows meaningful results to be obtained from the research.

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

Give details of the proposed sex of the animals, and rationale for the numbers of each sex[5][6]. Experiments should use the smallest possible number of animals required to answer the research question and should ensure that distress and suffering are avoided wherever possible. Applicants are strongly advised to consult with their animal care team in their HI when planning animal studies. Links to an online tool created to aid researchers including incorporating sex into study design and the ARRIVE checklist can be found in Appendix III.

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

Notes:

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

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

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

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

Useful links and resources are summarised in Appendix III.

The word limit is **4500 words.**

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

(If yes)

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

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

Award Scheme:

Year of previous submission:

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

2.5.5 Project Management

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

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

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

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

Are you including PPI in your application?

If Yes

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

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

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

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

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

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

If No

Please explain why PPI is not relevant to your project.

The word limit is **600 words**.

2.5.7 Gender and/or Sex Issues in the Research Project

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

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

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

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

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

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

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

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

The word limit is **400 words.**

2.5.8 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.

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

2.5.9 Biobanking

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

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

You must submit a completed **Infrastructure Agreement** form with details of the biobank. Please describe how you will ensure good practice for biobanking components in this project, with particular regard to quality of sample collection, processing, annotation and storage. Please reference relevant guidelines/standards you will use. Where material will be obtained or stored for a future research purpose, or where you will use material previously obtained for another purpose, please refer to the latest Recommendation of the Council of Europe[7]. Some useful links are in Appendix III. The word limit is **400 words**.

2.5.10 Potential Safety Risks and Ethical Concerns

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

2.5.11 Dissemination and Knowledge Translation Plan

Include a clear dissemination and knowledge translation plan to indicate how the research outputs you anticipate producing during and after your project will be disseminated and shared and made openly accessible, in line with HRB Open Access Policy[8]. 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[9].

Applicants are advised to consider the following:

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

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

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

- 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 project/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/).

The word limit is **500 words**.

2.5.12 FAIR Data Management and Stewardship

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

Please consider the FAIR Guiding Principles for scientific data management and stewardship: **F**indability, **A**ccessibility, **I**nteroperability, and **R**eusability[11].

1. **Data description and collection or reuse of existing data**: (a) What is the type, format and volume of data? (b) How will the data be collected, created or reused?

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

11 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).

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

The word limit is **500 words**.

2.5.13 IP considerations

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

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

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

2.5.14 References

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

For publications:

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

2.6 Project Description Figures

Any figures to support your Project Description can be included as a single additional upload. A **maximum of 5 figures**, which can be a combination of images, graphs, tables, scales, instruments, or surveys, can be included as a single document. They must not be embedded within the text of the Project Description. Additional references should not be included here. The maximum size is **2MB**. Files should be doc, docx, or pdf.

3 Details of Research Team

3.1 Lead Applicant Role

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

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

3.2 Co-Applicant Role

For each Co-Applicant (maximum 6), please identify the type of Co-Applicant they are here (Researcher Co-applicant, Knowledge User Co-applicant or PPI Co-applicant) and outline their role in this project on a day-to-day basis, including the amount of time to be dedicated to working on this project either as a percentage or as a proportion of a full time equivalent (FTE). The word limit is **250 words**.

3.3 Collaborators' Details

For each Collaborator (maximum 10), please outline their role in the project on a day-to-day basis including amount of time to be spent working on the project either as a percentage or proportion of a full time equivalent (FTE).

Note: For each collaborator a signed **Collaboration Agreement Form** must be provided. A template Collaboration Agreement Form is available with all application forms from the HRCI-registered research charity (maximum **250 words per Collaborator**).

3.4 Personnel

Give full details of all personnel to be funded through this project, including the Lead Applicant if relevant. State the percentage of time each person will spend on the project and describe what aspects of the proposed research they will be involved in over the lifetime of the project. Note that you must justify the nature of all research personnel relative to the scale and complexity of the project (please see section 5.1.4 Funded Personnel for more guidance on alignment between the chosen personnel and the project). If funding is requested for known personnel, please include the following details: Name, present position, academic and professional qualifications. The word limit is **400 words**.

Host Institution Letters of Support must be provided for (1) all Lead Applicant(s)- 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 HRCI-HRB Joint Funding Scheme 2024 award as a contract researcher; (ii) has a dedicated office and research space/facilities for which they is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team.

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

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

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 **400 words**.

4.2 Access to Research Infrastructures

Applications availing of the advice, research design, data management services and/or other forms of support from a Clinical Research Facility/Centre (CRF/CRC), other infrastructure unit (e.g., Centre for Applied Medical Imaging, Centre for Support and Training in Analysis and Research, HRB – Trials Methodology Research Network) or a biobank are required to provide additional information detailing the scope and nature of the engagement (this include national facilities and/or international facilities and units/networks where justified) at research design or implementation stages. The following information must be provided:

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

The word limit is **400 words**.

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

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

5 Project Budget

5.1 Project Duration, Budget and Start Date

Please indicate the expected length of the proposed project in months (minimum duration of 12 months and maximum duration is 36 months) and the proposed start date. The earliest start date is 01 October 2024.

The maximum total value of an award is **€300,000**. There is no set limit per annum: costs should be allocated in the year expected to occur.

5.2 Detailed project budget

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

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

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**.**

Only include direct costs in this application. HRB will apply a rate of 30% TDMC overhead on the HRB portion of research funding at time of contract for successful applications.

The total funding available will be €300,000 over 12-36 months. Allowable costs include:

1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with Host Institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scales for academic researchers http://www.iua.ie/research-innovation/researcher-salary-scales/. Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure. **Applicants <u>should</u> 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. The HRB does not provide salary or buy out time for collaborators
b) Employer's PRSI	Employer's PRSI contribution is calculated at 11.05% of gross salary.
c) Employer Pension Contribution	Pension provision <u>up to a maximum of 20%</u> of gross salary will be paid to the Host Institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
d) Student Stipend	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. **Annual increments are not provided within budget**.
2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, data access costs etc.

	Maintenance costs of animals are allowed for pre-clinical animal models only[13]. Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, Clinical Research Facilities support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form'. The following costs are ineligible and will not be funded: training courses/workshops, inflationary increases, cost of electronic journals. **Note:** Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
3. PPI Costs	All PPI-related costs for the grant except salaried personnel, such as but not limited to: • Compensating PPI contributors for their time (for example for time spent reviewing material/ participation in advisory groups) • Travel expenses for PPI contributors • Training in PPI in research • Costs associated with PPI contributors attending conferences or workshops • PPI event facilitator costs • Room hire for PPI events/meetings. • Hospitality for PPI events/meetings • Companionship or childcare costs for PPI contributors while attending events, meetings, etc. **Note:** PPI participants supported by salaries, should be listed and justified under the personnel heading. All costs should be in line with Host Institution policies
4. Equipment	Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €10,000. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e., overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified, and should not exceed €1,200. All costs must be inclusive of VAT, where applicable.
5. Dissemination Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge translation plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[14]. 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

[13] The maximum HRB allowable per diem rates for the maintenance of the most common strains of small animals are: mice (€0.50), other laboratory rodents (€1) and rabbits (€2) All per diem rates are inclusive of VAT at 23%. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis.

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

	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/year for national conference and €1,500/year for international conference.
6. FAIR Data Management Costs	Costs related to data-related and data management activities in line with best practice of data management and stewardship and the FAIR principles **incurred during the lifetime of the project**. Please see table below for further guidance.

Under each of the headings please **itemise each cost** and provide a brief but explicit **justification of the costs** claimed.

For Personnel Costs, please state the pay scale used and the level and point on the scale. This should be justified accordingly. For appointment of Research Fellows or Senior Research Fellows evidence of position must be provided at point of award.

Overhead contribution

Overheads in the HRCI-HRB Joint Funding Scheme are calculated at budget negotiations during contracting. The HRB will will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment, and capital building costs) for **laboratory or clinically based research** and 25% of Total Direct Modified Costs for **desk-based research**.

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

5.3 Additional guidance to FAIR Data Management Costs

People	Staff time per hour for data collection, data anonymisation, etc
	Staff time per hour for data management/stewardship support, training, etc
Storage and computation	Cloud storage, domain hosting charge
Data access	Costs for preparing data for sharing (e.g., anonymisation)
Deposition and reuse	Costs for depositing research data and metadata in an open access data repository
	Defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please further explain

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

5.4 Other Funding

Please indicate if you have submitted this, or a similar application, to another HRB scheme or funding body. If this application has been submitted elsewhere, please indicate which HRB scheme or funding

body, project title, result of submission or when outcome is expected and the amount of award. The word limit is **200 words**.

6 Ethical Approval and Approvals for Use of Animals

Ethical approval is required for all research work funded by the HRB that involves human participants, human material (including tissue) or animals . 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 Lead Applicant, Co-Applicant CVs and Collaborator Profiles

The templates provided in Form B1 must be used.

7.1 Lead Applicant CV

The Lead Applicant will be asked to complete a CV which details their gender, education, previous positions, ORCID and membership of profession bodies/councils.

ORCID

The HRB is now an ORCID member. Lead applicants are encouraged to include an ORCID iD.

Additional information will be sought for the following:

7.1.1 Publications and Funding Record

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

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

7.1.2 Supervisory experience

The Lead Applicant can include a brief summary of their supervisory experience to date. The word limit is **200 words.**

7.1.3 Additional evidence of experience and expertise relevant to this application

The Lead Applicant can describe any additional experience or expertise that will provide evidence of their ability to successfully lead the proposed project. Please use this opportunity to describe any career gaps in your CV. The word limit is **400 words**.

7.2 Co-Applicants CV

The Lead Applicant can add up to 6 Co-Applicants. For each Co-Applicant you must select whether they are a Researcher, Knowledge User or Public and Patient Involvement (PPI) Contributor co-

applicant for the purpose of the proposed research. The appropriate CV format (detailed in the application document B1) must be used depending on the contributor type defined.

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).

Please note that additional information regarding supervisory experience, if planning to supervise a postgraduate candidate, and their current position and status (contract or permanent) will be requested in the application form. The word limit is **400 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.

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. The word limit is **300 words**.

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

7.2.3 PPI Contributor Co-Applicants

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

7.3 Collaborators Profile

The Lead Applicant can add **up to 10 collaborators** per application. The Lead Applicant must enter **contact and CV details** for all Collaborators including name, contact information, institution or organisation, present position, employment history, profession and membership details of

professional bodies, **Publications and Funding Record** (if applicable) (5 most relevant publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) relevant to this application where the Collaborator has acted as Principal Investigator or Co-Applicant).

8 Supporting Documentation

The following documents must be included to complete the application:

Mandatory documents:

- Application Form (B1)
- Signature Pages for Host Institution and Lead Applicant
- Objectives and Deliverables Gantt Chart

If applicable:

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

Blank templates for the Collaboration Agreement Form and Infrastructure Agreement Form will be provided within the application pack. Signature pages will also be provided.

Submission of Applications

Please note the individual deadlines set for submission by each charity. If selected by the charity for submission to the HRB, that deadline will be 27 March 2024 at 13:00.

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

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

Checklist for submission

For all applications	
Part B1 Application form	
Part B2 Gantt chart	
Part B3 Figures supporting project description (1 document)	
Part D1 Signature pages for Lead Applicant	
Part D2 Signature pages for Host Institution	

Where applicable	
Part C1 Collaboration Agreement Form	
Part C2 Infrastructure Agreement Form	
Part C4 Letters of support	

Appendix II: HRB Funding Policies and Procedures

Access and support from research infrastructures

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

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

Public and Patient Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public and patients in the research that we fund[15]. Public and patient involvement in research means that the public and patients are involved in planning and doing research from start to finish and help tell the public about the results of research. PPI, as defined here, is distinct from and additional to activities which raise awareness, share knowledge, and create a dialogue with the public, and it is also distinct from recruitment of patients/members of the public as participants in research.

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

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

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

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

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

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

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

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

FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support open research[16] and open publishing directly through the HRB Open Research platform[17]. The HRB is driving the making of research data **FAIR** (**F**indable, **A**ccessible, **I**nteroperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles[18] 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[19], all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three

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

[17] https://hrbopenresearch.org/

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

[19] 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)[20]. 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[21].

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

Conflict of Interest

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

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

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

[21] https://hrcdc.ie/

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

Appeals Procedure

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

Privacy Policy and Retention Policy

To understand why we collect the information we collect and what we do with that information, please see our Privacy[23] and Retention Policies[24].

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

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

Appendix III: Resources/Useful Links

EVIDENCE SYNTHESIS

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

  https://evidencesynthesisireland.ie/

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

  www.thecochranelibrary.com

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

  https://www.campbellcollaboration.org/

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

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

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

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

CLINICAL RESEARCH INFRASTRUCTURES

- **All Ireland Hub for Trials Methodology Research**
  http://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/TheAll-IrelandHubforTrialsMethodologyResearch/
- **Centre for Advanced Medical Imaging, St James' Hospital Dublin**
  http://www.3tcentre.com/
- **Centre for Support and training Analysis and Research (CSTAR)**
  http://www.cstar.ie
- **Children's Clinical Research Unit**
  https://www.nationalchildrensresearchcentre.ie/childrens-clinical-research-unit/apply-for-support/
- **Clinical Research Support Unit, Limerick**
  https://www.ul.ie/hri/clinical-research-support-unit

- **Clinical Research Centre, Royal College of Surgeons in Ireland**
  https://www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/clinical-research-centre
- **Clinical Research Facility, University College Dublin**
  http://www.ucd.ie/medicine/ourresearch/researchenvironment/ucdclinicalresearchcentre/
- **Clinical Research Support Centre (Northern Ireland)**
  http://www.crsc.n-i.nhs.uk/
- **HRB Clinical Research Facility, Cork (HRB CRFC)**
  http://www.ucc.ie/en/crfc/
- **HRB Clinical Research Facility, Galway (HRB CRFG)**
  http://www.nuigalway.ie/hrb_crfg/
- **HRB Critical Care Clinical Trials Network (HRB Critical Care CTN)**
  ICC-CTN (iccctn.org)
- **HRB Irish Network for Children's Clinical Trials (in4kinds)**
  In4kids
- **HRB Primary Care Clinical Trials Network (HRB Primary Care CTN)**
  Primary Care Clinical Trials Network Ireland - HRB PC CTNI (primarycaretrials.ie)
- **HRB Trials Methodology Research Network (TMRN)**
  http://www.hrb-tmrn.ie
- **The National Clinical Trials Office (NCTO)**
  Email trials-ireland@ucc.ie
  https://ncto.ie/
- **Wellcome Trust-Health Research Board Clinical Research Facility, St James's Hospital (WT-HRB CRF SJH)**
  http://www.sjhcrf.ie/

BIOBANKING

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

  https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff
- **BBMRI-ERIC is a European research infrastructure for biobanking**

  https://www.bbmri-eric.eu/
- **OECD Guidelines on Human Biobanks and Genetic Research Databases**

  http://www.oecd.org/science/biotech/44054609.pdf
- **ISBER Best Practices for Repositories**

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

- **Molecular Medicine Ireland Biobanking Guidelines**

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

- **NCI Best Practices for Biospecimen Resources (2016 version)**

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

PUBLIC AND PATIENT INVOLVEMENT IN RESEARCH & RESEARCH PRIORITIES

- **The National PPI Ignite Network**
  https://ppinetwork.ie/

- **NIHR PPI resources**

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

- **Patient-Centred Outcomes Research Institute (PCORI)**

  http://www.pcori.org

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

  http://piiaf.org.uk/

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

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

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

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

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

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

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

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

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

- **The Involvement Matrix: A tool for researchers/project leaders to promote collaboration with patients in projects and research.**
  https://www.kcrutrecht.nl/involvement-matrix/

- **The Evaluation Toolkit: A resource designed for practitioners of the health sector, produced after the completion of a rigorous systematic review of patient and public engagement evaluation tools.**
  https://ceppp.ca/en/evaluation-toolkit/
- **GRIPP2 reporting checklists:** Tools to improve reporting of patient and public involvement in research.
  https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-017-0062-2#Tab1

USE OF ANIMALS IN RESEARCH

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

  https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam_en
- **Experimental Design Assistant (EDA) (online tool for design of animal experiments)**

  https://eda.nc3rs.org.uk/
- **PREPARE (Planning Research and Experimental Procedures on Animals: Recommendations for Excellence) guidelines**

  https://norecopa.no/prepare
- **ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines**
  https://arriveguidelines.org/
- **SYRCLE (Guidance and training on systematic review of animal studies)**

  https://www.syrcle.network/

  PROSPERO (Register for systematic reviews including animal studies)

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

GENDER AND/OR SEX ISSUES IN RESEARCH

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

  http://genderedinnovations.stanford.edu/case-studies-medicine.html
- **Gender Toolkit in EU-funded research for examples and guidance**

  http://www.yellowwindow.be/genderinresearch/downloads/YW2009_GenderToolKit_Module1.pdf
- **Sex/Gender Influences in Health and Disease**

  https://orwh.od.nih.gov/sex-gender/sexgender-influences-health-and-disease
- **Methods and Techniques for Integrating Sex into Research**

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

- **NIH Policy on Sex as a Biological Variable**

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

DATA MANAGEMENT AND SHARNG AND FAIR PRINCIPLES

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

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

- **FAIR data principles FORCE 11**

  https://www.force11.org/fairprinciples

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

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

- **Guidelines on FAIR data management plans in Horizon 2020**

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

- **FAIR at the Dutch centre for Life sciences**

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

- **Registry of Research Data Repositories**

  http://www.re3data.org/

RESEARCH DATA MANAGEMENT PLANS

- **Data Stewardship Wizard created by ELIXIR CZ and NL**

  https://dmp.fairdata.solutions/

- **DMPonline of the Digital Curation Centre (DCC), UK**

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

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

  https://dmptool.org/

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

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

- **Guidelines on FAIR data management plans in Horizon 2020**

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

KNOWLEDGE TRANSLATION RESOURCES

- **Health Service Executive Research & Development Main Page**
  https://hseresearch.ie/research-dissemination-and-translation/
- **Health Service Executive Research & Development: Knowledge Translation, Dissemination, and Impact A Practical Guide for Researchers**
  https://hseresearch.ie/wp-content/uploads/2021/04/Tools-and-templates-.pdf
- **Integrated Knowledge Translation (iKT) NUI Galway**
  https://www.nuigalway.ie/hbcrg/ikt/
- **The Canadian Institutes of Health Research:** Guide to Knowledge Translation Planning
  https://cihr-irsc.gc.ca/e/45321.html
- **Training Institute for Dissemination and Implementation Research in Health:** Open Access Course
  https://cancercontrol.cancer.gov/is/training-education/TIDIRC-open-access

CO-CREATION RESOURCES

- **ACCOMPLISSH Guide to impact planning**
  https://www.accomplissh.eu/publications-and-deliverables

  Working together to co-create knowledge: A unique co-creation tool – Carnegie UK Trust
  https://www.carnegieuktrust.org.uk/publications/working-together-to-co-create-knowledge-a-unique-co-creation-tool/

INFORMATION ON PERSISTENT IDENTIFIERS

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

  http://www.doi.org/registration_agencies.html
- **Handle: Assigning, managing and resolving persistent identifiers for digital objects and other Internet resources provided by the Corporation for National Research Initiatives (CNRI)**

  http://www.handle.net/
- **PURL: Persistent Identifiers developed by the Online Computer Library Center (OCLC). Since 2016 hosted by the Internet Archive**

  https://archive.org/services/purl/
- **URN: List of all registered namespaces provided by the Internet Assigned Numbers Authority (IANA)**

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

DATA REPOSITORIES

- **Registry of Research Data Repositories**

http://www.re3data.org/

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

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

- **Zenodo Data Repository (OpenAIR)**

  https://zenodo.org/

OTHER USEFUL LINKS

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

  https://creativecommons.org/choose/

Appendix IV: PPI Rating

The consensus PPI rating will be used to apply a correction to the consensus scientific score as per the Table below.

Rating	Description	Correction applied to the consensus scientific score
Excellent	You are very satisfied with the quality of the public and patient involvement in the application. PPI is evident from the early planning stages and throughout the lifetime of the award (if successful), including in decision-making at management level. Methods of involvement are innovative and maximise benefits. Planned PPI activities seem appropriately resourced in the budget.	0.5
Good	You are satisfied with the quality of the public and patient involvement in the application; some additional clarifications would have been helpful. PPI may not have started at the earliest stage of research planning OR included in decision-making at management level, but is well embedded in the application (if successful) at stages throughout its lifetime. Methods of involvement are tailored to the research. Planned PPI activities seem appropriately resourced in the budget.	0.25
Appropriate	You are reasonably satisfied with the quality of the public and patient involvement in the application. Methods of involvement are generic, some additional clarifications would have been helpful and/or PPI could potentially have been included to a greater extent from planning phase. Planned PPI activities seem appropriately resourced in the budget.	0
Fair	You are satisfied with some of the public and patient involvement provided in the application. PPI could potentially have been included at other stages throughout the lifetime of the award (if successful), methods of involvement are generic and/or planned PPI activities seem to be under resourced in the budget.	-0.25
Poor	You are not satisfied with the public and patient involvement in the application because important information seems to be lacking. PPI does not appear to have been a significant part of the planning for the award (if successful). Planned PPI activities seem to be under resourced in the budget.	-0.5