Health Research Charities Ireland/Health Research Board Joint Funding Scheme 2022

Instructions to Applicants

Guidance Notes

Deadline	Key Dates and Times*
Charities Open Call	DD Month YYYY
Charities Internal Application Deadline	DD Month YYYY
HRB Application Deadline	DD March 2022

*Dates to be confirmed

Contents

1 Introductory Notes

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.

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.

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, 134 projects have been jointly funded by member charities and the HRB in ten 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 2022 call of the HRCI/HRB Joint Funding Scheme.

1.1 Objective

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 value of the application to the charities' strategic aims must be clearly demonstrated. Projects are expected to create new knowledge and evidence of benefit to health or healthcare.

1.2 Scope

This scheme provides funding for clearly defined research projects in areas of strategic relevance to each individual charity. HRCI/HRB awards will be up to a maximum total award value of **€300,000** for projects from 12 up to 36 months. Funding outside of Ireland **may be allowable** where there is no established research capacity in Ireland (e.g. for the case of rare diseases).

The joint 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. Guidance notes on the application form are available in Appendix I.

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

- 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
- 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

Please note that applicants 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

[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*

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 HRB/charity-funded research.

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

2 Eligibility Criteria of Principal Investigator, Co-Applicants and Collaborators

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 official Collaborators. For studies that require a lot of coordination applicants should consider the appointment of a study manager or coordinator (for small studies this may be one of your Co-Applicants, rather than a dedicated post).

Co-applicants and collaborators from outside the Republic 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, patients, and carers in the research that we fund (see Section 7 Public Patient and Carer Involvement (PPI) in Research for further details). **PPI contributors** are welcome as **Co-Applicants or official 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.

2.1 Principal Investigators

The Principal Investigator (PI) **will serve as the primary point of contact during the review process and during the award. The PI** will be responsible for the scientific and technical direction of the research programme and **has 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 contract governing the award.**

The Principal Investigator must:

- Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland (the "Host Institution") as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable. **OR**
- Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award, for which he/she 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 such as published book chapters, reports to government 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.

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

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

Only one application per Principal Investigator to this scheme will be considered.

Where the PI is based outside of Ireland, where possible they should seek Co-applicants or Collaborators in Ireland in order to build capacity here. PIs based outside of Ireland must ensure that a ***signed Warrant*** *is submitted at the time of application, confirming that their institution will sign up to HRB Terms and Conditions (see section 2.6).*

2.2 Co-Applicant

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

A Co-Applicant has a well-defined, critical and substantial role in the conduct and steering of the proposed research. Co-Applicants from outside of the Republic of Ireland are welcome where this is appropriately justified in terms of added value for the project. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards his/her own salary if they are in salaried positions. However, 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 if they are contract/independent investigators. PPI contributors should be named as Co-applicants where justified by their level of involvement (**up to a maximum of 6 Co-Applicants can be listed).**

Note: It is not mandatory to have 6 Co-Applicants, but this is to allow for flexibility should this be appropriate.

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

2.3 Official Collaborator

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

Note: It not mandatory to have 10 Collaborators, this is to allow for flexibility should this seem appropriate.

In addition, each official collaborator must complete a **Collaboration Agreement Form.** A template Collaborator agreement form is available and this must;

- Detail the full nature of the collaboration and how the Collaborator will be involved in the proposed research and specifically the value they will add
- Confirm the individual or organisation's commitment to the proposed project
- Identify the value, relevance and possible benefits of the proposed work to the Collaborator

- State the period of support
- Detail how the results of this collaboration will be disseminated
- Details of the costs requested, where relevant, and appropriate justifications

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

A 'Data controller' refers to a person, company, or other body that decides how and why a data subject's personal data are processed. If two or more persons or entities decide how and why personal data are processed, they may be 'joint controllers', and they would both share responsibility for the data processing obligations[2].

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, intellectual property rights, reporting and access to data and samples when working up collaboration agreements.

2.4 Funded Personnel

Applicants must demonstrate clearly 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 given strong consideration. Reviewers will thoroughly assess the level of baseline experience matched with the supervisory and up-skilling arrangements proposed in scoring the application.

Unlike the HRB's fellowships programmes, this scheme is not framed as a training initiative. Where junior personnel registered for a higher degree are proposed to work on projects, Principal Investigators must carefully consider the complexity, scale, objectives and dependencies of the project and the skills, expertise and experience level required to carry it out, especially if involving one or more PhD student(s). In such instances, PIs are also strongly encouraged to think about the suitability of such projects for PhD students, in terms of delivering a clearly identifiable original research project or the potential difficulties in clustering various pieces of work packages for a PhD thesis. The HRB strongly encourages four-year support for PhD candidates in line with other HRB-funded doctoral training programmes such as SPHeRE[3], ICAT[4] and Collaborative Doctoral Awards (CDA). Please see the Frequently Asked Questions for further details on PhD candidates in PHR or HSR projects.

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

[3] Structured Population and Health Services Research Education Programme http://www.sphereprogramme.ie/

[4] Wellcome HRB Irish Clinical Academic Training Programme https://icatprogramme.org/

2.5 Public, Patient and Carer Involvement in Research

What is PPI?

The HRCI/HRB promotes the active involvement of members of the public, patients and carers in the research that we fund. Public, Patient and Carer Involvement (PPI) is research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them[5]. PPI, as defined here, is distinct from and additional to activities which raise awareness, share knowledge and create a dialogue with the public, and it is also distinct from recruitment of patients/members of the public/carers as participants in research.

PPI represents an active partnership between members of the public, patients and carers and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising throughout or at particular 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.
- 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 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.
- 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.

[5] https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-help-with-research/

We strongly advise that you consult with the charity, the PPI Ignite Network Ireland or your Host Institution who will be able to provide guidance and support in PPI in research. The PPI Ignite Network Ireland has offices located in the following seven Host Institutions: DCU, NUIG, RCSI, TCD, UCC, UCD, UL.

2.6 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 **Principal Investigator** but it may be another organisation/institution designated by the research team, where it is clearly justified. In order to be eligible to apply for funding, an Institution must be an **approved** HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for research performing organisations to be approved as HRB Host Institutions can be found on the HRB website[6].

Host Institution Letters of Support must be provided for (1) all Principal Investigators in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*Host Institution - insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB ILP award as a contract researcher; (ii) has an independent office and research space/facilities for which he/she 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.

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

Host Institution for the award is a recognised research institution approved by the HRB under its Host Institution Policy. It is typically that of the Principal Investigator, but it may be another organisation/institution designated by the research team, where it is clearly justified.

The Host Institution is typically located in the Republic of Ireland. Funding researchers in Host Institutions outside of Ireland may be allowable where there is no established research capacity in Ireland (e.g. for the case of rare diseases).

For international Host Institutions that are **public or private universities** a warrant must be given at application stage that they can comply with HRB terms and conditions (T&C available on the HRB web

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

page at www.hrb.ie). For international Host Institution that are **not public or private universities**, the Host Institution will agree that as part of the acceptance documentation if successful they will have to provide information as per the HRB Host Institution application form.

2.7 Access and support from Research Infrastructures

Applications availing of the advice, and support from a Clinical Research Facility/Centre (CRF/CRC), Clinical Trial Network (CTN), other infrastructure unit (e.g. Centre for Applied Medical Imaging, CSTAR), are required to provide additional information detailing the scope and nature of the engagement (this includes national facilities and/or international facilities and Units/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/CTN, will be asked to justify why they have not done so.

2.8 FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB supports **open research**[7] and open publishing directly through the **HRB open research platform**[8]**.** 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[9] provide guidelines 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[10], all successful applicants are required to submit a completed data management plan (DMP) to the HRB until up to three months after the award start date, and a final updated version of the DMP with the last annual report.

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

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

[8] https://hrbopenresearch.org/

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

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

- Applicants will have to provide an outline of their plans for data management and data sharing in the full 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.

2.9 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 to **consent** 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 **consent** 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.

2.10 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)[11]. 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

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

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 [12].

2.11 Research on Research

The HRB is currently 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.

3 Funding Available and Duration

HRCI/HRB awards will be up to a maximum total award value of **€300,000** for projects from 12 months up to 36 months. Eligible costs include personnel costs, student stipend and fees, direct running costs, FAIR data management costs and dissemination costs. Overheads of 30% of Total Direct Modifiable Costs will be added to the portion of the research funded by the HRB (see section 5.2).

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.

Note: The scheme does not fund the salary and related costs of tenured academic staff within research institutions (including buy out from teaching time etc.).

4 Application Review Process and Review Criteria

4.1 Application Process

All applications must be made to the HRCI-registered research charity on or before their own set closing dates. All application documents must be completed in font Calibri Size 11. It is the responsibility of the Principal Investigator to ensure that applications are completed in full, and all the necessary documentation is received by the charity on or before the closing dates indicated.

Note: ***Please note each document will have a size limit of 2MB.***

4.2 Review Process

HRCI/HRB is committed to an open and competitive process underpinned by international peer review. Each charity will conduct a peer review process by soliciting reviews of applications from at least three international experts in the subject area of the proposed research. Peer reviewers will focus on the

[12] https://hrcdc.ie/

stated assessment criteria for the call and will provide comments as well as a score which is visible to the charity. Anonymised peer reviews will be collated and forwarded to applicants.

4.2.1 Applicant Response

The Principal Investigator with the support of his/her team will be provided with a time-limited opportunity to respond to peer-reviewers comments. The peer-reviewers' comments will be made available to PIs by email. Each PI and team will have **10 working days only** to submit their response to the charity they applied to, and the response has a maximum word count of **2000 words (including figures and references)**. The response will be used by the charity to inform their short-listing process, and in the case of short-listed applications will be provided to members of the Panel in advance of their face-to-face meeting alongside the application and the peer-reviewers' comments.

This phase of the assessment process is extremely important, and the response will likely play a critical role in whether an application ultimately gets recommended for funding or not. It provides an opportunity to address any factual errors, conceptual misunderstandings or differences of opinion that can be perceived as weakness or concerns. It also provides the PI and team with an opportunity to take on board any constructive feedback that may help to improve the application, if funded, or future grant applications.

The response should be succinct yet clear and comprehensive. It should acknowledge and/or address each of the concerns and/or weaknesses described in the reviewer's feedback. If the applicant team disagrees with a reviewer's statement they should explain why and provide additional information. If the applicant team cannot address an issue, they should at least acknowledge it. Responses that could be seen as argumentative should be avoided. Please remember that peer reviewers and panel members volunteer their own time in reviewing grant applications.

4.2.2 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.

4.2.3 HRCI/HRB Panel Review

Applications put forward by the participating charities will be considered by a jointly-appointed HRCI/HRB Panel. This Panel will include broad scientific expertise, as well as PPI Panel members and

will consider applications from across all the charities. Each application will be reviewed by a lead and secondary scientific panel member and by two PPI panel members.

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.

Scientific Panel members will review the strengths and weaknesses of the application on the stated assessment criteria for the call 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.

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
- Public and Patient and Carer Involvement in development of and throughout the project
- Research Design - inclusion of research participants (where applicable)
- Dissemination of the Proposed Work

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

Applications recommended for funding by the grant panel will be submitted to the Board of the HRB for approval. A summary of Panel member's comments and the panel discussion comments will be issued to the Principal Investigator following the conclusion of the review process.

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

4.2.4 Review Criteria

- **Scientific Quality and Innovation (50% of marks)**
    - Important research question *(panel review stage only)*
    - Evidence supports need for proposed project
      Design and methodology appropriate

- **Expertise and Research Environment (30% of marks)**
    - Applicant team expertise and experience relevant for project
    - Supports, infrastructure, environment

- **Feasibility (20% of marks)**
    - Project staffing and funding

- Project plan and risk mitigation for project delivery

Applicants need to score well across these criteria to be successful. An assessment of your PPI approach may influence the assessment of any or all criteria depending on the nature of the proposed research.

4.2.5 HRB Gender Policy

In line with international best practice, the HRB Gender Policy recognises the responsibility the HRB has to supporting 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.

4.2.6 Award Contracts

Host Institutions of successful applications will be offered multi-party contracts between the HRB, the HRCI partner(s) and the approved Host Institution setting out the respective roles and responsibilities of the parties and governing the research project. The HRB Terms and Conditions will govern the award in its entirety. Additional special conditions may apply.

5 Appeals Procedure

The HRB's procedure for appealing funding decisions is available at
http://www.hrb.ie/funding/funding-schemes/before-you-apply/relevant-policies/.

6 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[13] and Retention Policies

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

7 Timeframe

Activity	Date
HRB Call Opening	1 September 2021
Charity Calls Open	Varies
Applicant Response to Peer Review comments	From mid-January 2022
Charity Selection Panel	January- February 2022
Joint Funding Panel Meeting	May 2022
HRB Board Approval	June 2022
Contract negotiations and contracting	July/August 2022
Earliest Start Date	September 2022

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 Principal Investigator to provide all supporting documentation within the 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 procedure for appealing funding decisions is available at **http://www.hrb.ie/funding/funding-schemes/before-you-apply/relevant-policies/.**

Appendix I Guidance on the Application Form

These notes must be read in conjunction with the Application Form and are designed to help you provide the required information. Please ensure that you complete the Application Form in full. Do not leave a question blank, but if you feel that a question is not applicable to you, please state that this is the case. ***Please note each document (Application Form, Signature Page, Supporting Figures, Gantt chart etc.) will have a size limit of 2MB.***

Project Title (mandatory, maximum 20 words)

This should be both clearly descriptive and concise and should reflect the aim of the project.

SECTION 1: DETAILS OF PRINCIPAL INVESTIGATOR AND CO-APPLICANTS

1.1 Principal Investigator Details

Includes name, contact information, host institution, present position and profession.

1.2 Co-Applicant Details

Includes co-applicant type, name, contact information, host institution or organisation, present position and profession.

1.3 Host Institution for the award

This institution is normally that of the Principal Investigator, but it may be another organisation/institution designated by the research team, where this is clearly justified. The funders must be fully satisfied that the institution can account appropriately, over time, for any funding awarded. You are requested to state the name of institution and to provide the name and contact details of either the Dean of Research/CEO/equivalent authorised personnel of the institution in your application.

SECTION 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, say why you think it is important to complete this piece of work 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 and/or charity 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. The aims and hypotheses of the project should be conveyed with clarity. The objectives of the project and what the work is expected to establish should be described. Ideally 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 (maximum five keywords)

Please choose up to five keywords that specifically describe your area of research.

2.5 Project Description

The Project Description* should include the following:

- Research Question
- Current knowledge and Background to the Area
- Overall Aim
- Objectives and Deliverables (including Gantt chart or alternative)
- Research Design and Methodological approach
- Project Management
- Public and Patient and Carer involvement in the research
- Gender and/or sex issues in the research project
- Impact Statement
- Biobanking
- Potential Risks and Ethical Concerns
- FAIR data management and stewardship
- Dissemination and Knowledge Exchange Plan
- IP Considerations

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

*Any figures to support the project description must be provided in a *single additional document* up to a maximum file size of 2MB.

2.5 a Research Question

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

2.5b Current Knowledge and Background to the area

Describe the background to the research application and detail the size and nature of the issue to be addressed. Include evidence from the literature and give references to any relevant systematic reviews. Where available, include a description of any pilot work, professional and consumer consensus studies already undertaken. Summarise the importance of the proposed research and describe the anticipated outputs, outcomes and impact of the proposed research, indicating the anticipated timescale for any proposed benefits to be realized. Please provide a clear explanation of the problem to be addressed and why it is important and timely, especially in an Irish context. Be aware that the peer reviewers reading your application will be based outside of Ireland, so it is important to describe the current healthcare delivery context in Ireland when discussing issues around need, relevance, timeliness and feasibility. Explain how the research has the potential to contribute to the health and wellbeing and who will benefit from this research. The word limit is **1200 words**.

2.5c Overall Aim

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

Objectives and deliverables

Please add at least 3 individual objectives. Objectives should be SMART (specific, measurable, achievable, realistic and time-bound). For each objective please list a subset of deliverables which will be used to measure progress. Note that the stated objectives and deliverables will be used to monitor progress throughout the lifetime of the award. Timelines should be set against objectives/deliverables in your Gantt chart. The word limit is **60 words for each objective and 150 for deliverables**.

You must provide 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. PhD submission) and roles and responsibilities of the Principal Investigator team etc. Please note that the preparation and submission of Data Management Plans should also be added as

deliverables/milestones of the Programme. The Gantt chart should be provided as a separate file with a maximum file size of 2MB.

2.5d Research Design and Methodological Approach

Summarise the proposed research plan, providing descriptions of individual project/work streams or 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. Give details of the proposed sex of the animals, and rationale for the numbers of each sex[14]. Please refer to the ARRIVE checklist for animal studies referenced in Appendix II.

Note: 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. See the Science Europe Report on "Improving Science Quality through the Replacement, Reduction and Refinement of Animals in Biomedical Research and Development" for a recent discussion[15]. Links to an online tool created to aid researchers in experimental design of studies involving animals can be found in Appendix II, in addition to links to recently updated Guidance and checklists for animal studies from 3Rs. The appendix also gives details of registers for systematic reviews involving animal studies.

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.**

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

[15] http://www.scienceeurope.org/uploads/PublicDocumentsAndSpeeches/SCsPublicDocs/WS_Report_3Rs_Final_web.pdf

- 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 II.

The word limit is **4500 words**

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

(If yes)

- Award Scheme:
- Year of previous submission:

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

2.5e Project Management

Please describe how the project will be managed. The role of each applicant team member and research personnel should be clearly outlined. Describe any oversight, advisory or governance structures that are crucial to delivery of the project, including the trial steering committee and the 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**.

2.5f Public and Patient and Carer Involvement in the Research Project

The HRCI/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, this is participation of the public rather than involvement. 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 II. 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, patients or carers 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**.

2.5g Gender and/or sex issues in the research project

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 II for resources on gender and sex considerations in research applications.

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

The word limit is **400 words.**

2.5h Impact Statement

Describe the anticipated outputs and outcomes of the proposed research. Please provide details on the likely **impact** of this research project 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.**

2.5i Biobanking

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

Please describe how biobanking within this project will be in compliance with the General Data Protection Regulation, in particular in relation to consent.

If Yes, 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[16]. Some useful links are in Appendix II. The word limit is **400 words.**

2.5j Potential 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.**

2.5k Dissemination and Knowledge Exchange Plan

Include a clear dissemination and knowledge exchange plan to indicate how the research outputs you anticipate producing during and after your project will be disseminated, shared and made openly accessible, in line with HRB Open Access Policy[17]. 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[18].

Applicants are advised to consider the following:

1. The HRB has a mandatory Open Access publication policy; demonstrate how you plan to make all publications open access.
2. 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?
3. Describe any plans for technology transfer.
4. Describe how the findings of this research are to be publicised to the HSE or international health community/organisations in a manner that will optimise impact on health policy and/or practice.
5. Please reference aspects of the project/study undertaken to maximise chances of adoption beyond the term of the award.

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

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

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

Types of publication routes[19]:

- **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 paid 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**.

2.5l Outline of 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: Findability, Accessibility, Interoperability, and Reusability[20].
With the support of data stewards or other data-related services support in the institution (typically library and ICT and digital service, etc) all Principal 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.

1. **Data description and collection or reuse of existing data**: (a) What is the type, format and volume of data? (b) How will the data be collected, created or reused?
2. **Documentation and data quality**: (a) What metadata and documentation will accompany the data (b) Will you make sure globally resolvable unique, persistent identifiers are in use (e.g. DOI)?; 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?

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

[20] 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).

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 data will be preserved long term (e.g. data repository, archive (c) What methods or software tools are needed to access data? (d) Who will be responsible of data management (e.g. data steward) and the time needed for data management and for making data FAIR (costs will also be added under the budget section).

The word limit is 500 words.

2.5m IP considerations

The Principal Investigator 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[21]. 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 **500 words**.

2.6 References cited in the project description (maximum 30)

This section of your application should demonstrate that you are familiar with recent published research and other scholarly activity related to the application. It is through the inclusion of up-to-date references that you can demonstrate your awareness of the current state of knowledge in your chosen discipline. Please use the convention in the example when entering references:

Smyth, B.P. & O'Brien, M. (2004) Children Attending Addiction Treatment Services in county Dublin, 1990-1999. *European Addiction Research,* 10(7455) pp. 68-74.

SECTION 3: DETAILS OF RESEARCH TEAM

[21] National Intellectual Property Protocol, 'Inspiring Partnership- the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland'

3.1 Principal Investigators 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 Principal 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-Applicants Role

For each Co-Applicant, please identify the type of Co-Applicant they are here (Researcher Co-applicant, Knowledge User Co-applicant, or PPI Co-applicant) and outline their role in 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). Describe the specific contribution and responsibilities of the Co-Applicant. The word limit is **250 words**.

3.3 Collaborators Role

For each Collaborator, please outline their role in the project. The word limit is **250 words**.

3.4 Personnel

Give full details of all personnel to be funded through this project. 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. If funding is requested for known personnel, please include the following details: Name, address, present position, academic qualifications, professional qualifications.

Give a detailed justification for the nature of the research personnel relative to the scale and complexity of the project. The word limit is **400 words**.

SECTION 5: 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, methods, trial management 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 Infrastructure

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, CAMI, Centre for Support and Training in Analysis and Research (CSTAR)) 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) should justify why they have chosen not to access such support.

Where applicable a signed **Infrastructure Agreement Form** (Appendix 1 of the Application Form) must be provided. Failure to provide an Infrastructure Agreement Form(s) will result in the application being deemed ineligible. Electronic signatures are acceptable.

SECTION 5: PROJECT DURATION AND BUDGET

5.1 Project Duration and Budget total

Please indicate the expected length of the proposed project in months and provide a summary and justification of the costs and duration associated with the project. The minimum duration is 12 months and the maximum is 36 months. It is important to note that the budget requested and award duration must reflect the scale and nature of the proposed research.

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 Project budget

Use Table 1 to provide a **summary of the Total Costs** requested and Table 2 to justify each amount requested.

A **full detailed breakdown** of **costings** and **justification for all funding** is required for items listed under each subheading. You are strongly advised to seek guidance from the research office/finance office in the Research Institution before completing this section of the form. HRCI/HRB will not provide additional funding in the case of either under-estimates or over expenditure.

Funds will be provided for the following:

1. **Personnel costs**	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with host institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scales for academic researchers http://www.iua.ie/research-innovation/researcher-salary-scales/. Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure. **Applicants should include annual pay increments for staff and related costs (pension contribution, 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. Please find IUA pay scales at https://www.iua.ie/research-innovation/researcher-salary-scales/. In line with the proposed new pay agreement for State employees please apply a salary contingency of 1% per annum from 1st Oct 2021 and 1st October 2022 and of 2% from 1st October 2023 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% for 2020

c) Employer Pension Contribution	Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution. If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
d) Student Stipend	The HRB student stipend is €18,000 per annum (tax exempt) as recommended by current IUA scales.
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.** Please note only personnel in receipt of a stipend are eligible to receive a student fee contribution.
2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs etc. Maintenance costs of animals are allowed for pre-clinical animal models only[22].

[22] 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 21.5%. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis.

	Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, biobanking, Clinical Research Facility support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying '**Infrastructure Agreement Form**' upload. Costs associated with involving members of the public or patients in your research e.g. consultation workshops, costs of participation in advisory groups, travel expenses etc. should be charged to running costs. Data management costs for the duration of the project should be charged to running costs. The following costs are ineligible and will not be funded: training courses/workshops (with the exception of training in public and patient involvement in research) for funded research personnel, 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. 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 Principals **incurred during the lifetime of the project**. Please see table below for further guidance.
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 <u>will not</u> 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. 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 exchange plan. Data sharing costs can be included here. Please refer to the HRB policy on Open Access to Published Research[23]. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary.) **Publications:** Typically, the average HRB contribution towards publication costs is €1,750/per article or **HRB Open Research:** rapid open-peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee. (www.hrbopenresearch.org) **free of charge**. **Conferences:** We envisage that conference costs will be typically around €500 per national conference and €1,500 per international conference.
6. Overhead Contribution	**This applies only to the HRB-funded part of the award and will be added to successful applications during contract negotiations.** In accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modifiable Costs (TDMC excludes student fees, equipment and capital building costs) for both lab/clinical and desk-based research The following items are included in the overhead contribution: recruitment costs, bench fees, office space, software, contribution to gases, bacteriological media preparation fees, waste fees, bioinformatics access.

Additional guidance to FAIR Data Management Costs

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

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

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

5.5 Other Funding

Give details of any other financial support available for this or other related projects e.g. existing national or international studies. Indicate project title, funding agency or sponsor, the amount of award and a summary of the project. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review. The word limit is **300 words**.

SECTION 6: ETHICAL AND REGULATORY APPROVAL, AND 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.

SECTION 7: PRINCIPAL INVESTIGATOR AND CO-APPLICANT CVs AND COLLABORATOR PROFILES

7.1 Principal Investigator CVs

The CV templates provided must be used for the Principal Investigator. The CV template includes sections on career profile, publication and funding records. CVs can be a maximum of 5 pages and should be broken down as follows: Section 1 (max 2 pages) + Section 2 (max 1 page) + Section 3 (max 2 pages)

7.2 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 **500 words**.

7.3 Co-Applicant CVs

The CV templates provided must be used for all Co-Applicants. Co-Applicants should select the template that corresponds to their role on the project: Researcher Co-Applicant, Knowledge User Co-Applicant or PPI Contributor Co-Applicant. If a Co-Applicant contributes from more than one perspective, please select the dominant role.

Researcher Co-Applicant CV template includes sections on relevant publications, relevant funding and supervisory experience. Knowledge User Co-Applicant CV template includes sections on influencing decision making within knowledge user organisations and evidence of experience and expertise relevant to this application. PPI Co-Applicant CV template includes a section on experience and expertise relevant to this application.

7.4 Collaborator Profile

Provide Collaborator details including name, present position, and contact information**.** With regard to Collaborator Publications and Funding Record, where applicable please provide **five most relevant publications** in peer-reviewed journals and give details of any **past or current grants** held (including HRCI or HRB grants) relevant to this application where the collaborator has acted as Principal Investigator or Co-Applicant.

In addition, each official Collaborator must complete a **Collaboration Agreement Form.** A template is made available, and this must:

- Detail the full nature of the collaboration, how the Collaborator will be involved in the proposed research and specifically the value he/she will add
- Confirm the individual or organisation's commitment to the proposed project
- Identify the value, relevance and possible benefits of the proposed work to the Collaborator
- State the period of support
- Detail how the results of this collaboration be disseminated

Note: Research Institution Letter of Support must be provided for **(1) all Principal Investigators in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary.** The formal letter on headed notepaper and signed by the Head of School/Research Centre/Hospital must include the following information; [*Research Institution – insert name*] which is the research institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognised by the research institution upon receipt of the HRCI/HRB award as a contract researcher; (ii) has a dedicated office and research space/facilities for which he/she is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise post-graduate students and post-doctorate researchers.

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).

Submission

Please ensure that you have completed all the relevant sections of the application form. Once you have submitted your application, you cannot edit or unsubmit it. All applications must be submitted to the HRCI-registered research charity on or before their own set closing dates.

Signature Page

All applications for funding must be signed by the Principal Investigator and Co-applicants and the Dean of Research/CEO/equivalent authorised personnel of the Research Institution using the signature page provided in Part D1 and D2. ***Electronic versions of signatures are acceptable (Size limit of 2MB).***

Part C3 includes a warrant, which must be signed by **Host Institutions outside of Ireland** if applicable.

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 principal investigator	
Part D2 Signature pages for Host Institution	

Where applicable

Part C1 Collaboration Agreement Form	
Part C2 Infrastructure Agreement Form	
Part C3 Signed Warrant for international Host Institutions only	
Part C4 Letters of support	

Appendix II References/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

- **The National Clinical Trials Office**

  Email trials-ireland@ucc.ie

- **Health Research Board Clinical Research Facility, Cork**

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

- **Children's Clinical Research Unit**

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

- **Health Research Board Clinical Research Facility, Galway**

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

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

  http://www.sjhcrf.ie/

- **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/

- **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

BIOBANKING

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

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

- **BBMRI-ERIC is a European research infrastructure for biobanking**

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

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

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

- **ISBER Best Practices for Repositories**

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

- **Molecular Medicine Ireland Biobanking Guidelines**

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

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

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

PUBLIC, PATIENT AND CARER INVOLVEMENT IN RESEARCH & RESEARCH PRIORITIES

- **The National PPI Ignite Network** Local offices located in DCU, NUIG, RCSI, TCD, UCC, UCD and UL

- **HRCI Resource: PPI in the Joint Funding Scheme (case studies)**

  https://hrci.ie/ppi-in-the-joint-funding-scheme/

- **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

USE OF ANIMALS IN RESEARCH

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

  https://www.nc3rs.org.uk/experimental-design-assistant-eda

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

  https://www.nc3rs.org.uk/arrive-guidelines

- **SYRCLE (Systematic review of animal studies, register 2014-2017)**

  https://www.radboudumc.nl/en/research/departments/health-evidence/systematic-review-center-for-laboratory-animal-experimentation

- **PROSPERO (Register for systematic reviews including animal studies 2018)**

  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

- **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

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

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

- **Zenodo Data Repository (OpenAIR)**

  https://zenodo.org/

FAIR/OTHER USEFUL LINKS

- **Main FAIR Principles**

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

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

  http://www.rcuk.ac.uk/documents/documents/concordatopenresearchdata-pdf/
- **Tool that helps to select and apply a license to a resource, provided by Creative Commons**

  https://creativecommons.org/choose/