Rare Diseases Research and Innovation Catalyst Awards (RDCat) 2023

Guidance Notes

Guidance Notes

Key Dates & Times (subject to Board approval)	
Application Open	25 April 2023
Application Closing Date	27 June 2023 @13:00

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

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

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1 Introduction

1.1 Background

The Health Research Board (HRB) Strategy (2021-2025)[1] sets out a lead role for the HRB to invest in a strong and supportive environment for health research, and add value to existing HRB and national investments by shaping the Irish contribution to EU co-funding initiatives and EU partnerships, including in rare diseases.

The HRB has a long track record of pro-actively supporting rare disease research since the early 2000s. The HRB introduced one of the world's first Rare Disease Fellowship schemes, and in the last ten years, the HRB-HRCI Co-funding scheme has invested €7M in rare disease projects. Over that decade, the HRB has enhanced Ireland's participation in European coordinating initiatives and Joint-Transnational calls.

Rare diseases and paediatric research are prime examples of research areas that can strongly benefit from coordination at a European and international level to achieve scale and to overcome fragmentation, leading to better use of data and resources, faster scientific progress and competitiveness, and deliver better patient care. No single institution, laboratory, or even country is likely to encounter a sufficient number and diversity of patients with a given rare disease to be able to advance research alone.

To this end, the HRB is a member of the European Joint Programme on Rare Diseases (EJPRD) which brings over 130 institutions from 35 countries to create a comprehensive, sustainable ecosystem allowing a virtuous circle between research, care and medical innovation. HRB contributes funding for successful Irish research partners in EJPRD Joint Transnational calls and is represented on the Governing Board.

Discussions are at an advanced stage to shape a new EU Rare Diseases Partnership[2], which is planned to begin in 2024 and if funded[3], will ensure the continuity of the work of EJP RD. The HRB is participating in these discussions to ensure the input of stakeholders from Ireland. From a strategic perspective, the EU Rare Diseases Partnership is an opportunity to build on prior national investments to advance research in rare diseases. In Autumn 2022, the Department of Health confirmed support for Ireland to participate in the EU Rare Diseases Partnership (RDP) which, if funded, will commence in 2024 (see Appendix I for details).

Much of the research activity in the planned EU Rare Diseases Partnership will build on European Reference Networks (ERNs)[4] established by the European Union as they are important hubs for research on rare diseases and provide a basis for collaborative research across Europe (see Appendix II for details). In 2022 Ireland secured approval to link clinical sites across Ireland into 18 of the ERNs[5]

[1] *https://www.hrb.ie/strategy-2025/*
[2] *https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe_en*
[3] *A formal proposal for the Rare Diseases Partnership will be submitted to the European Commission during 2023 and will be subject to international peer review*
[4] https://health.ec.europa.eu/european-reference-networks/overview_en
[5] https://www.gov.ie/en/press-release/fb5a2-minister-donnelly-welcomes-approval-for-irish-hospitals-to-join-european-reference-networks-on-rare-diseases/

and this expanded ERN membership has huge potential to generate new rare disease research partnerships across Europe.

1.2 Rare Diseases Research and Innovation Catalyst Call (RDCat)

This call aims to bring together all relevant stakeholders in a single award to ensure that Ireland is better placed to engage in rare diseases research activities and the planned EU Rare Diseases Partnership through the strategic use of the RDCat award.

The HRB research-focused investment should complement national/EU investments to support clinical activities associated with the ERNs and complement recent investment in the Rare Disease Clinical Trials Network. HRB investment should stimulate and formalise further co-investment in rare disease research; it should be additive and not replace existing funding.

Through this new call, the Rare Diseases Research and Innovation Catalyst award, HRB is seeking a single application on behalf of a consortium of partners across the island of Ireland, as part of a coordinated approach to maximise preparedness for the EU Rare Diseases Partnership, provide targeted research supports for clinical sites in Ireland as they transition to active members of the ERNs, and boost levels of rare disease R&I in Ireland.

2 Aim and Objectives

The overall **aim** of the RDCat call is to optimise readiness for the planned EU Rare Diseases Partnership and ensure that research and innovation can deliver better outcomes for rare disease patients in Ireland.

The **objectives** of this scheme are to:

- Catalyse and strengthen research and innovation capability in partnership with the five main clinical sites in Ireland hosting ERNs, according to prioritised needs.
- Maximise the likelihood that the ERN Clinical Leads can engage in research and innovation activities, including but not limited to clinical trials[6].
- Enhance and extend rare disease research collaborations across the island of Ireland, and across Europe (and beyond).
- Prepare ERNs and other stakeholders in Ireland to engage in the research and transversal activities associated with the EU Rare Diseases Partnership, including research data infrastructure for R&I.
- Ensure relevant Rare Diseases research stakeholders involved, and PPI embedded throughout supported activities.
- Grow the number of rare disease patients in Ireland with opportunities to participate in research.

[6] Funding for individual rare disease research projects, or trials and interventions is not provided through this award. Such funding is expected to come through separate, competitive sources

3 Scope of Call

The scheme will provide stimulus funding to create a more supportive environment for rare diseases R&I, with the aim of increased capacity for pre-clinical, clinical, population health and health services research, and to promote clinical trial readiness.

Investment should catalyse R&I activity in Ireland and drive significant engagement with the planned new Rare Diseases Partnership. The award can provide targeted research support for ERN sites in Ireland as they transition to active members of the ERNs. Leveraging Ireland's new ERN membership, research collaborations within and outside Ireland should be fostered and enhanced to increase levels of rare disease R&I. It should enable RD research stakeholders to engage in collaborative research and other transversal research activities under the Rare Diseases Partnership, including on research data infrastructures, and identifying patient priorities for research.

This scheme aims to boost research into rare diseases, regardless of disease area, ideally as part of a broad-based portfolio (e.g., patient-oriented, clinical, population health, health services). HRB investment should be prioritized to have the maximum impact. RDCat activities should link to international efforts as appropriate, and support early-career researchers to build further capacity for rare disease research in Ireland with opportunities for relevant exchange, training and education activities for investigators (complementary to EJPRD/Irish Clinical Academic Training[7] etc).

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

3.1 Expected outputs/outcomes from the RDCat award:

- Coordinated engagement with the Rare Disease Partnership, including on research calls, and data infrastructure for R&I.
- Increased visibility of RD research to early career researchers in Ireland.
- Increased numbers of early-career researchers completing exchanges, training activities, COST actions[8] etc in rare diseases.
- Increased number of researchers generating preliminary data on which to base concrete rare disease research proposals.
- Coordinated, quality-managed, approach to populating and maintaining contact database[9](s) of patients (families, carers) interested in rare disease research or PPI opportunities.
- Increased number of competitive proposals being submitted by Ireland to e.g.:
    - Rare Diseases Partnership, Joint Transnational Calls (RD, PM, etc)
    - HRCI/HRB joint funding scheme, HRB Project grants, Clinical trials and SDAP etc
    - Innovative Health Initiative II, Science Foundation Ireland, Wellcome, charity-funded research.
- More ERN Clinical Leads and investigators engaging in R&I.

[7] https://icatprogramme.org/

[8] *https://www.cost.eu/cost-actions/what-are-cost-actions/*

[9] *Where assets such as a contact database containing personal data are supported through this award, they must be maintained within the public sector: Host Institution or hospital as appropriate.*

- New and enhanced national and international research collaborations and networks in rare diseases.
- Increased capacity for multi-disciplinary rare disease research.
- Better connectivity across the ERNs to boost patient-focused research in RD, including on data infrastructures for R&I.
- Development of PCOMs/PROMs, patient research priorities/preferences as appropriate
- Increased involvement of patients in influencing research priorities.
- RD research portfolio is better aligned with patient needs.
- Greater number of participants from Ireland on ERN Patient Advocacy Groups (ePAGs).
- Greater accessibility to research studies for patients and healthy volunteers.

3.2 Out of scope

Out of scope for this scheme:

- Funding for individual research projects, trials and interventions is not provided.*
- Building work, fit-out of buildings, or major pieces of equipment.
- Applications which are solely or predominately developing the infrastructure for biobanking, databases or **patient registries.****
- Direct costs of biobanking.
- Applications from individuals applying for, holding, or employed under a research grant from the tobacco industry.

** **Funding for individual rare disease research projects, or trials and interventions is not provided through this award.** Such funding is expected to come through separate, competitive sources (such as the HRB Definitive Interventions and Feasibility Awards scheme, HRB Investigator-Led project grants, HRCI/HRB Joint Funding Scheme, EJP-RD and ERAPerMed Joint Transnational Calls among others).*

***Due to the critical importance of having a sustainable funding model and appropriate governance for patient registries[10], this HRB Catalyst Award should not be used to establish new registries or to subvert the costs of maintenance of existing registries. Consideration can be given, however, to expanding and optimising the use of registries to support rare disease research. Patient registries should be funded through other mechanisms and may count as co-investment as long as they are aligned with ERN standards and intended to be interoperable.*

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

4 Funding Available, Duration and Start Date

The HRB RDCat scheme will provide funding up to a maximum of **€3,000,000** (inclusive of overheads) for a single award with a duration of 36 months, quality permitting. The award must commence in 2023, and the latest start date is 1 December 2023.

[10] http://hrci.ie/wp-content/uploads/2019/10/Patient_Registry_Guide_7-18_LR__002__Modified_Acknowledgements.pdf

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

The RDCat investment should drive a strategic and coordinated approach to engaging with the RDP and enable greater levels of engagement in R&I by Clinical Leads, other investigators, and other RD research stakeholders. Public and Patient Involvement activities are expected to form part of the award. Funding may for example be used for backfilling some sessions for the RDCat Lead, a dedicated role in coordination, or a data coordinator role, training for the consortium/early-career researchers, Research Fellows to assist with writing of grant applications, or other areas as appropriate and justified.

4.1 Eligible costs

Eligible costs may include:

- ***Contributions to Personnel costs*:*** *for example,* costs of backfill of approximately 10% for RDCat Lead**, RDCat Research Coordinator (to ensure coordination across Ireland and connectivity with external initiatives), Research Data Coordinator, training and outreach coordinator (ensuring leverage of EJPRD/Partnership offerings), PPI liaison and support (including for activities of ePAG), Research Fellows to provide research support to the ERN leads/co-leads etc.;
- ***Running costs***: *for example,* travel costs, PPI costs, meeting costs, training and exchange bursaries, networking events, access to expertise in Data Management, evidence synthesis, provision for proof-of-concept seed funding***, costs to develop PCOMs/PROMs or costs to ascertain patient research priorities and needs;
- ***Dissemination and knowledge exchange costs***
- ***Overhead contribution*** of 30% TDMC*****.

** HRB recognises current challenges in hiring personnel, and noting the three-year duration of award, the team may wish to adapt/expand existing roles.*

*** HRB will fund up to 1 session per week of protected time for RDCat activity work for the RDCat Lead, or a Co-Applicant, where appropriately justified.*

**** A description of the proposed use of seed funding must be set out within the application for peer reviewers to determine the relevance and added-value.*

***** PCOMs/PROMs development should be linked to existing gaps that are impeding research/limiting impact and align with work in the ERNs as appropriate.*

****** Total direct modified costs (excluding equipment or fees). The apportioning of overheads should be agreed between the partner institutions during the preparation of the application. The HRB expects this to be formalised for successful applications.*

4.2 Co-funding

Co-funding investment is expected from academic, hospital or other partners (cash and/or in-kind contribution) to ensure organisation-level commitment to these goals and to further sustainability of

research and innovation activities in rare diseases. **HRB funding is not intended as a replacement for existing financial support from elsewhere**; this award is intended to stimulate further investment. Ideally, contributions should support integration of research activity into the healthcare system.

In the region of 0.5 FTE contribution to RD Catalyst Coordinator cost (or similar role in the award) would be welcomed as cash or in-kind. For this purpose, HRB will count contributions from HIs, hospitals or associated charities/patient organisations. A letter of commitment in respect of the co-funding should be uploaded to GEMs as part of the application.

Where **contributions from industry partners** are foreseen, the consortium should have a policy on managing such contributions from industry collaborators.

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

5 Eligibility Criteria

One application should be made on behalf of a consortium of individuals and organisations, that is representative of a national endeavour and can credibly lead this initiative on behalf of the Irish rare disease research community, including representation of the ERN clinical sites.

The Lead Applicant and Co-Applicants must come from a variety of different centres in Ireland. The RDCat call requires researchers from **three or more centres/organisations in Ireland** to be eligible to apply. The appropriate number of centres/organisations involved will depend on the scale and nature of the proposed activities.

In addition to typical HRB eligibility requirements, the **Lead Applicant** for the RDCat call is expected to be active in rare disease research, and with experience of health service delivery in Ireland.

While representation of ERN Clinical Leads/Co-Leads within the applicant team is not mandatory, there must be a mechanism for inclusion **of ERN Clinical Leads** and **the patient voice** in the award governance structures. An International Strategic Advisory Board is suggested to provide an outside perspective to the consortium and aid with horizon scanning.

The **Host Institution (HI)** for the HRB award is a HRB recognised host institution. It is normally that of the Lead Applicant, but it may be another organisation/institution designated by the consortium, where it is clearly justified.

Please note, this call is not open for Host Institutions from Northern Ireland.

5.1 Applicant Team

Applications should be made on behalf of a team with necessary breadth and depth of expertise and experience to deliver the proposed activities.

The applicant team must clearly demonstrate that the appropriate and relevant partners are involved in order to achieve the objectives, and minimum deliverables as specified. Given the need for relevance to needs of rare disease patients, PPI team members are expected for this call.

Co-applicants and collaborators from **outside Ireland** are permitted where their participation is well justified, and clearly adds value to the award.

Industry partners or **industry associations** are welcome to join as collaborators (see section 5.1.3 for further details), provided they provide an integral and discrete contribution to the proposed activities.

5.1.1 Lead Applicant

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

In addition to typical HRB requirements for the Lead Applicant, the Lead Applicant for the RDCat call is expected to be active in rare disease research, and with experience of clinical service delivery in Ireland. They should be a credible lead for the initiative, ideally with a proven track record in multi-institutional collaborative initiatives.

The Lead Applicant **must**:

- Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable **or**
- Be a contract worker recognised by their Host institution as a person who will have a dedicated office space for the duration of award, for which they will be fully responsible, **or**
- Be an individual who will be recognised by their Host Institution upon receipt of the award as a contractor as defined above. 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 relevant to this award by:

a) Demonstrating expertise in relation to rare disease research. Where appropriate, they may provide evidence of outputs such as research articles, published guidelines, working group outputs, reports to government and/or any other relevant outputs that are relevant to the aims and objectives of this award.
b) Demonstrating record of independence by showing that they have secured at least one peer-reviewed research grant for a research project/s, as either the Lead Applicant or a Co-Applicant. Funding received for travel to seminars/conferences and/or small personal bursaries will not be considered in this regard.
c) Demonstrating a record of independence by showing that they have taken a lead role in a relevant initiative.
d) Show evidence that they possess the capability and authority to successfully lead the applicant team.

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

5.1.2 Co-Applicants

Co-applicants are expected to have a well-defined, critical and substantial role in terms of planning the initiative and assisting the Lead Applicant with the leadership and management of the RDCat award. Co-applicants will be expected to take leadership/co-leadership on delivery of specific work packages. Collaborators should be individuals or an organisation that provides an integral and discrete contribution (either direct or indirect) to the proposed activities.

A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards their own salary if they are in salaried positions. However, researchers in contract positions/independent investigators, Knowledge Users[11] and PPI contributor Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to the research for the duration of the award. (**up to a maximum of 10 Co-Applicants can be listed).**

Note: It is not mandatory to have 10 Co-Applicants, but this is to allow for flexibility should this be appropriate.

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

5.1.3 Collaborators

An official Collaborator is an individual or an organisation who will have an integral and discrete role in the proposed award 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.

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

[11] 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, policymaker, health professional, clinician or other who can make significant changes to policy or practice.

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 award, evidence of commitment and access must be demonstrated by having the Data Controller or key Gatekeeper of a study included as a Collaborator.

5.1.4 Funded Personnel

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

Roles and responsibilities of funded personnel must be differentiated and clear.

Unlike the HRB's research career schemes, this scheme is not framed as a training initiative and is not suitable for students in pursuit of a higher degree. The HRB strongly encourages four-year support for PhD candidates in line with other HRB-funded doctoral training programmes such as SPHeRE[12], ICAT[13] and Collaborative Doctoral Awards (CDA).

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. The Host Institution agrees to provide support for the management of a multi-site award, including e.g., agreeing collaboration agreements between partner institutions, management of payments to co-applicants' institutions.

HRB Host Institution status is a requirement to submit an application under all HRB award schemes. The **Host Institution for the award** is normally that of the **Lead Applicant** but it may be another organisation/institution designated by the research team, where it is clearly justified. In order to be eligible to apply for funding, an Institution must be an approved HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for research performing organisations to be approved as HRB Host Institutions can be found on the HRB website[14].

Please note that for this call, the lead Host Institution must be a recognised Host Institution from the Republic of Ireland.

Host Institution Letters of Support must be provided for **(1) all Lead Applicants in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary.** The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*Host Institution - insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract

[12] *Structured Population and Health Services Research Education Programme* http://www.sphereprogramme.ie/
[13] *Irish Clinical Academic Training Programme* https://icatprogramme.org/
[14] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/

which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB RDCat 2023 award as a contract researcher; (ii) has an independent office and research space/facilities for which they is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the team. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

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

7 Application, Review Process and Assessment Criteria

7.1 Grant E-Management System (GEMS)

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

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

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

The **HRB Gender Policy** came into effect on 1 June 2016[15]. In line with international best practice the HRB has a responsibility to support everyone to realise their full potential, 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(s) in all HRB panels where possible. Gender will also be considered when appointing the position of Panel Chair.

7.2 Review Process

GEMS will close the application stage automatically at the stated deadline and timeline (**27 June 2023 @ 13:00**).

Applications will be initially checked for eligibility by HRB staff members. Where an application is deemed to be out of scope the Chair of the international grant selection panel will be consulted to confirm the recommendation.

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

Following the initial eligibility check, each eligible application submitted to this scheme will undergo a two-stage review process.

Phase 1 - Public Review

For each application, the HRB aims to receive written feedback from at least two public reviewers. **Public reviewers** will only assess the quality of PPI in the application and will provide comments and an overall rating which will be shared with the panel. Public reviewers will not provide a score.

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

Phase 2 - Panel Review

International peer reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. An international grant selection panel will be convened with members selected based on the expertise and skillset needed for the RDCat call.

The panel will review the strengths and weaknesses of the application relating to the review criteria detailed below and submit comments prior to the panel meeting. The Applicant team will be invited for interview at the panel meeting and will have access to the panel reviews and public reviews of their application ahead of the interview taking place. The interview will begin with a short presentation by the applicant team followed by a Q&A session where the applicant team should aim to address any concerns raised by panel members. More details on the interview will be provided to the applicant team closer to the time.

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

Successful applicants are expected to score well in all review criteria. While PPI is not a stand-alone assessment criterion, it may influence scores under any criterion as relevant to the application.

The recommendations of the Interview Panel will be presented for approval at the next scheduled HRB Board meeting. When the Board of the HRB has approved the process and recommendations, HRB staff will contact the applicants to notify them of the outcome. A summary of Panel Member's comments and the panel discussion comments will be issued to the Lead Applicant following the conclusion of the review process.

7.3 Assessment Criteria

The following assessment criteria, which have equal weight, will be used to assess applications **by the panel reviewers**. The successful application will be expected to **rate highly in all criteria**.

The **Criteria for Assessment** of the applications are:

Added-value of HRB investment

- Proposed investment has clear added-value above and beyond any research activities, collaboration or networking currently taking place
- HRB support complements and leverages other investments

- Existing RD research capabilities and collaborations in Ireland harnessed to ensure impact for patients.

Quality and relevance of proposed award activities

- Investment is strategic and targeted to boost rare disease R&I in Ireland
- Spectrum of activities/supports is appropriate to increase RD research in areas of patient need
- Coordinated approach to engagement with the Rare Disease Partnership evident
- Proposed work is prioritised and phased appropriately
- Budget and resource details proposed are clear and appropriate.

Strength of collaboration

- Clear collaborative approach to decision making, strategy
- Appropriate stakeholders involved to maximise impact for patients
- Appropriate award management and governance
- Clear, strong links with relevant HIs/Hospitals/ERNs/patient organisations evident in governance arrangements.

Team and environment

- Suitable applicant team, with complementary expertise and experience
- Roles and responsibilities of proposed team are clear
- Proposed team can deliver on objectives of the award
- Representation from HSE, and PPI Contributors as appropriate
- Accessibility and suitability of facilities, infrastructure and other supports, as appropriate.

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

8 Timeframe

Date	
25 04 2023	Call Opening
27 06 2023 @13:00	Call Closing
Jul-Sep	Panel and public written review
Early Sep 2023	Panel Review Meeting
Sep 2023	HRB Board Decision
Oct -Nov	Contracting
01 12 2023	Latest start date

9 Contacts

For further information on the Rare Diseases Research and Innovation Catalyst Awards contact:

Dr Caitriona Creely

Head of International Cooperation, Evaluation and Targeted Programmes

Research Strategy and Funding

Health Research Board

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

Appendix I: European Rare Diseases Partnership

Rare diseases are not that rare. While the occurrence of each disease is low, as a group there are over 7,000 different types of rare diseases and disorders, with more being discovered each day[16]. Globally, it is estimated that as many as 350 million people suffer from rare medical conditions, 30 Million in Europe and over 300,000 women, men and children in Ireland[17,18]. Even though only a relatively low number of people may be affected by a particular disease, it can present a disproportionately large strain on healthcare and social services[19]. Because they are rare it means national experience can be lacking and indeed diagnosis can be long delayed.

Rare diseases research has a lot of inherent challenges. They are often called "orphan" diseases where treatment is unlikely to generate sufficient profit to justify research and development costs by drug companies, and lack of broad public awareness historically resulted in little/no Government funding[20]. Recruiting sufficient patients is challenging and discovering new medicines for rare diseases is more expensive than for common diseases.

In the last decade, increased EU and global focus and investment in rare disease research and trials is making a difference to rare disease patients and their families. Importantly, research investment in rare diseases has a multiplier effect; studying the role of a gene in a rare or undiagnosed disease can help our understanding of related common diseases.

The aim of the planned Rare Diseases Partnership (RDP) is to improve the health and well-being of 30 million persons living with a rare disease in Europe, by making Europe a world leader in rare disease research and innovation and delivering concrete health benefits to rare disease patients (through better prevention, diagnosis and treatments). The ambition of the RDP is set out in a "concept paper"[21], published in 2022.

To leave no one behind, the planned Rare Diseases Partnership will deliver an RD multi-stakeholder ecosystem by supporting robust patient need-led research, developing new therapies and diagnostic pathways, utilizing the power of health and research data and spearheading the digital transformational change in RD research and innovation.

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[16] https://rarediseases.org/rare-diseases/

[17] Nguengang Wakap, S., Lambert, D.M., Olry, A. et al. Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database. Eur J Hum Genet 28, 165–173 (2020). https://doi.org/10.1038%2Fs41431-019-0508-0

[18] Byrne, N., Turner, J., Marron, R. et al. The role of primary care in management of rare diseases in Ireland. *Ir J Med Sci* 189, 771–776 (2020). https://doi.org/10.1007/s11845-019-02168-4

[19] Lopez-Bastida J, Oliva-Moreno J, Linertova R, Serrano-Aguilar P. Social/economic costs and health-related quality of life in patients with rare diseases in Europe. *Eur J Health Econ.* (2016) 17:1–5. doi: 10.1007/s10198-016-0780-7

[20] https://www.ema.europa.eu/en/glossary/orphan-medicine

[21] https://commission.europa.eu/system/files/2022-02/ec_rtd_he-partnerships-rare-diseases.pdf

Finally, the RDP will structure the European Research Area (ERA) on rare diseases by supporting the coordination and alignment of national and regional research strategies, including the establishment of public-private collaborations, through research activities all along the R&I value chain, ensuring that the journey from knowledge to patient impact is expedited, thereby optimising EU innovation potential in rare diseases.

This will be enabled by a tripartite mission to be accomplished by 2031:

- Bring supporting R&I resources and support from across Europe under one roof so that every high-quality RD research project will benefit from cross-disciplinary expertise, goal-oriented study planning and efficient execution.
- Enable every consenting patient living with a rare disease to be findable and enrolled in a suitable clinical study which will necessitate having access to regulatory and FAIR principles compliant data; generating advances in prevention, diagnosis and understanding of diseases, and developing treatments.
- Make Europe a global leader in rare disease research by providing a suitable infrastructural and regulatory support as well as a significant increase in investment to spur innovation, leading to job creation and optimising EU competitiveness in R&I.

In addition to support for transnational research on rare diseases, transversal activities supporting rare disease research are proposed. These are envisaged to include:

- engage with interoperable, federated, evolving and scalable RD infrastructure of data, samples, resources and tools with necessary critical mass for meaningful RD research & innovation,
- access to high-value, ethically and regulatory compliant data tools and services tailored to needs of RD research community,
- Mentoring support, Capacity building (including train the trainer),
- alignment of national RD strategies with EU objectives,
- Support for Patient-Centered Outcome Measures (PCOMs) and Patient-Reported Outcome Measures (PROMs) guideline development, and a platform to support policy debates linked to RD research (drug regulation, diagnostics, medical devices).

Please note that the EU Rare Disease Partnership is currently in planning, with funding subject to approval by the European Commission's review processes. Further details of the Rare Diseases Partnership will emerge during 2023, with a public consultation on the Strategic Research and Innovation Agenda expected during May 2023. The applicant team is expected to review this and orient their application to maximise opportunities presented by the Rare Diseases Partnership to the extent possible.

Appendix II: European Reference Networks (ERNs)

These cross-border networks bring together centres of expertise and reference centres of European hospitals to tackle rare or low prevalence and complex diseases and conditions that require highly specialised healthcare. Membership of an ERN provides a portal not only for clinicians and patients to consults with European experts, but a clear platform for collaboration on research, including clinical trials, with partners across Europe. In the current planning discussions for the proposed Rare Diseases Partnership, emphasis has focused across Europe on the inherent challenges of conducting rare disease clinical studies and trials, including the lack of research-related capacity, capabilities and skills at hospital sites and lack of academic-clinical networks that could leverage and expand the research capacities of European Reference Networks.

Recognising the importance of joining European efforts, and with promotion from the Rare Disease National Office Ireland (HSE), in 2022 Ireland secured approval to link clinical sites across Ireland into 18 of the ERNs[22]. The five main clinical sites hosting ERNs are Beaumont Hospital, Children's Health Ireland, Mater Hospital, St. Vincent's University Hospital, and Tallaght University Hospital. In addition to anticipated positive impact on clinical care for rare disease patients, Ireland's new ERN membership has huge potential to generate new collaborative research partnerships across Europe to address the challenges of rare diseases.

[22] https://www.gov.ie/en/press-release/fb5a2-minister-donnelly-welcomes-approval-for-irish-hospitals-to-join-european-reference-networks-on-rare-diseases/

Appendix III: Detailed Guidance on the Application Form

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

Please refer to the GEMS Technical Guidance Note for further information.

The Lead Applicant must create the application, but it can then be jointly completed with named Co-Applicants. Lead Applicants can register on GEMS and they will receive an email to confirm their registration and log in details. The Lead Applicant can then add information on their contact and CV details in 'Manage My Details' section of GEMS.

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

Once logged in to GEMS applicants are taken directly to the Home page which is the starting point to create a new Grant application. Please select the Rare Diseases Research and Innovation Catalyst Awards (RD CAT) 2023. ***Further details for completing each of the main sections of application form is provided below:***

Declaration of Interests

Please declare any conflict of interests or potential conflict of interest that a member of the applicant team may have, e.g. a personal or commercial interest in the award.

Host Institution and Signatory Notification

The HRB expects that applicants contact their Host Institution as soon as they begin their application, and engage with them to facilitate a review of the application. Please liaise with your Host Institution regarding any internal deadlines.

Host Institution

The Host Institution (HI) for the HRB award is a HRB recognised host institution. This is normally that of the Lead Applicant, but it may be another organisation/institution designated by the research team, where it is clearly justified.

Please note, this call is not open for Host Institutions from Northern Ireland.

An up to date list can be found at all times at **http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/**

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

Signatory Notification (within Host Institution)

Once the Host Institution is selected at the initial stages of application creation this will allow the Lead Applicant to notify the authorised signatory (Dean of Research or equivalent person authorised to endorse research grant applications for the Host Institution) in that Host Institution of the Lead Applicant's intention to submit an application to the RD Cat 2023. The signatory's details are pre-populated in the system so the applicant just needs to click 'NOTIFY' within GEMS. We recommend

that you **notify the HI signatory** of your intention to apply as soon as possible in the application process. The signatory will receive an email from GEMS with the name and email details of the Lead Applicant and if they have any queries or clarifications they can engage directly to resolve them with the Lead Applicant. The HI signatory must confirm their willingness to participate as HI for the application through GEMS and once they do this a PDF of the application will be available for them to review with a view to them ultimately approving the final version for submission to the HRB.

1. Rare Diseases Research and Innovation Catalyst Awards (RD CAT) 2023 Summary

1.1 Award Title

This should be descriptive and concise and should reflect the aim of the award.

1.2 Award Duration

Please indicate the award duration: up to 36 months.

1.3 Start Date

Please indicate the anticipated start date. The latest start date for awards is 1 December 2023

1.4 Proposal Abstract

This should be a succinct summary of the proposed award. The aims of the award should be conveyed with clarity. The objectives of the award and what the work is expected to establish should be described. Ideally it provides a clear synopsis of your proposal and should set the proposed work in context. The word limit is **500 words**.

1.5 Lay summary

This lay summary is similar to the proposal abstract in that you are asked to describe what you propose to do, say why you think it is important to complete this work, and how it will be done. 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. 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 published on the HRB website. The word limit is **300 words**.

2. Lead Applicant, Co-Applicants and Collaborators details

Please read Section 5. Eligibility Criteria of these Guidance notes before completing this section of the application form.

One application should be made on behalf of a consortium of individuals and organisations, that is representative of a national endeavour and can credibly lead this initiative on behalf of the Irish rare disease research community, including representation of the ERN clinical sites in the award governance.

The Lead Applicant and Co-Applicants must come from a variety of different centres in Ireland. The RDCat call requires researchers from **three or more centres/organisations in Ireland** to be eligible to apply. The appropriate number of centres/organisations involved will depend on the scale and nature of the proposed activities.

Representation of ERN Clinical Leads/Co-Leads within the applicant team is not mandatory (there must be a mechanism for inclusion **of ERN Clinical Leads** and **the patient voice** in project governance structures, see Section 6.1).

2.1 Lead Applicant

Please read Section 5.1.1 Lead Applicant of these Guidance notes before completing this section of the application form. In addition to typical HRB eligibility requirements, the **Lead Applicant** for the RDCat call is expected to be active in rare disease research, and with experience of health service delivery in Ireland.

Details are requested about the Lead Applicant, including their position, employment status (contract or permanent), whether they are seeking salary-related costs, and their experience. The Lead Applicant's **contact and CV details** (Name, contact information, institution, present position, profession) are managed in the 'manage my details' section of GEMS and are automatically included in any application created involving that individual.

2.1.1 Lead Applicant Publications and Funding Record

The Lead applicant is asked to add their **5 most relevant publications to this application** on which they have acted as senior author. Please use the publication selection tool in this section to select the 5 most relevant publications. Please note your full list of publications will not be pulled through from your CV. Please state the total number of your peer reviewed publications. You should also include your **5 most relevant funding** awards as Lead Applicant or co-applicant.

2.1.2 Evidence of experience and expertise relevant to this application

Please provide evidence of activity in rare disease research, and experience of health service delivery in Ireland and evidence to support leadership of this award as per the call requirements.

The Lead Applicant may also wish to include any additional experience or expertise that will support their application. For example, evidence of expertise they may have relating to international collaborative research, commercialisation, industry involvement, PPI activities, and influencing healthcare practice and/or policy. The word limit is **400 words**.

2.2 Co-Applicants

Please read Section 5.1.2 Co-Applicants of these Guidance notes before completing this section of the application form. The Lead Applicant can add up to 10 Co-Applicants to an application by entering their name on GEMS.

If the Co-Applicant is already registered on GEMS, the system will find them and will allow the Lead Applicant to select them. Alternatively, a co-applicant can be added manually by entering their name and email details. GEMS will send them an email with login details for completing the registration

process and will inform them that they have been invited by the Lead Applicant to participate on the application as a co-applicant.

Registered co-applicants can then manage/update their contact details and CVs in 'Manage My Details' and they can decide whether to accept or reject their participation and consent to the application being submitted jointly in their name. If a co-applicant rejects participation on an application the Lead Applicant is informed and may revise the application accordingly. Co-applicants whoaccept to participate in an application can edit the application. The system will flag through a pop-up warning if another user is working on the application form at the same time. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data but it advisable that they contact the other person directly to avoid losing data when applying the override function.

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

2.2.1 Research Co-Applicants

Each co-applicant should ensure the following **contact and CV details** in the 'manage my details' section of GEMS are up to date and correct (Name, Contact information, Institution). This information will be automatically included in this application. including their 5 most relevant publications in peer-reviewed journals, their relevant funding record (past or current grants held, including HRB grants), and their current position and status (contract or permanent). **Please note Co-Applicants 5 most relevant publications must be entered directly onto the application form and will not be pulled through from their CV.**

Co-Applicants are also asked to provide any additional evidence of expertise they may have relating to the activities within this award. The word limit for this is **200 words**.

Please state the total number of your peer reviewed publications.

Letters of Support: **Host Institution**

Host Institution Letters of Support must be provided for **(1) all Lead Applicants in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary.** The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*Host Institution – insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB RDCat 2023 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. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

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

2.2.2 Knowledge User Co-Applicant

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

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

Knowledge User Co-Applicants will also be asked to provide information regarding **Additional evidence of experience and expertise relevant to this application**. For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health, evidence of Patient Public Involvement in their knowledge user role, and roles/responsibilities as a constructive and effective change agent. The word limit is **400 words**.

2.2.3 PPI Contributor Co-Applicants

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

2.3 Collaborators Details

Please read Section 5.1.3 Collaborators of these Guidance notes before completing this section of the application form.

The Lead Applicant can add up to 10 collaborators per application. Unlike co-applicants, the information for collaborators is not automatically drawn from the 'Manage my Details' section of GEMS but must be entered by the Lead Applicant. The Lead Applicant must enter **contact and CV details** for all collaborators including name, contact information, institution, present position, **Publications and Funding Record** (if applicable) (five most relevant publications in peer-reviewed journals and details of 5 past or current grants held (including HRB grants) relevant to this application where the collaborator has acted as Lead Applicant or Co-Applicant).

In addition**,** for each collaborator a signed **Collaboration Agreement Form** must be provided. A template Collaboration Agreement Form is available for download from GEMS. Forms must be completed, signed, dated and uploaded where indicated on HRB GEMS. Electronic signatures are acceptable on letters/forms that are uploaded on GEMS.

3. Team Details

3.1 Applicant Group

Please read Section 5.1 Applicant Team of these Guidance notes before completing this section of the application form.

3.1.1 Lead Applicant Role

Please read Section 5.1.1 Lead Applicant of these Guidance notes before completing this section of the application form.

1. Firstly please indicate the **current commitment** to research/clinical/teaching/other, either as a percentage or a proportion of a full time equivalent (FTE).
2. Outline the role of the Lead Applicant in the award on a day-to-day basis including amount of time to be spent working on the award either as a percentage or proportion of a full time equivalent (FTE).

The word limit is **200 words**.

3.1.2 Co-Applicant's Role

Read Section 5.1.2 Co-Applicants of these Guidance notes before completing this section of the application form. Co-applicants are expected to have a well-defined, critical and substantial role in terms of planning the initiative and assisting the Lead Applicant with the leadership and management of the award. Co-applicants will be expected to take leadership/co-leadership on delivery of specific work packages.

In this section you are asked to outline the role of all Co-Applicants in the award on a day-to-day basis including amount of time to be spent working on the project either as a percentage or proportion of a full time equivalent (FTE). **Note: It is not mandatory to have 10 Co-Applicants, but this is to allow for flexibility should this be appropriate.**The word limit is **100 words per Co-Applicant**.

Note: research infrastructures are not expected to be listed as co-applicants in applications. Details should be included in Infrastructure Agreement Forms as detailed in Section 3.3.

3.1.3 Collaborator's Role

Please read Section 5.1.3 Collaborators of these Guidance notes before completing this section of the application form. Include details of all collaborators involved in the award and state their contribution to the project and the amount of time to be spent working on the project either as a percentage or proportion of a full time equivalent (FTE). The word limit is **75 words per Collaborator**.

3.1.4 Funded Personnel

Complete the table with details of all personnel expected to be employed to work on this award. Specify the personnel type, state the time each person will spend on the project, either as a percentage or proportion of a full time equivalent (FTE), indicate which work packages(s) they will be involved in, describe their role over the lifetime of the award. If known you are asked to provide their name, present position and qualifications. As co-funding is expected for this award, please clarify **whether you are requesting funding/part-funding from HRB for each position.** The word limit is **75 words per person**.

Give a justification for requested personnel relative to the scale and complexity of the award.

Unlike the HRB's research career schemes, this scheme is not framed as a training initiative and is not suitable for students in pursuit of a higher degree. The HRB will not fund Masters or PhD candidates through this award. The HRB strongly encourages four-year support for PhD candidates in line with other HRB-funded doctoral training programmes such as SPHeRE[23], ICAT[24] and Collaborative Doctoral Awards (CDA).

[23] Structured Population and Health Services Research Education Programme http://www.sphereprogramme.ie/
[24] Irish Clinical Academic Training Programme https://icatprogramme.org/

3.2 Strength and Complementarity of the Applicant Group

Applications should be made on behalf of a team with necessary breadth and depth of expertise and experience to deliver the proposed activities. Given the need for relevance to needs of rare disease patients, PPI team members are expected for this call. Please describe how the team has the collective expertise, competencies, and experience to successfully deliver this award, under the leadership of the Lead Applicant. The word limit is **800 words**.

3.3 Infrastructure and Support

Please detail arrangements with local hospitals and local/regional/national infrastructures regarding access to expertise, facilities or space in order to successfully deliver the award.

Please describe the approach to coordination with existing research infrastructures for the purposes of delivering the RDCat activities such as: the HRB Rare Disease Clinical Trials Network, other relevant Clinical Trial Networks, the National PPI Network, the Clinical Research Facility/Centre (CRF/C)s, The National Clinical Trials Office (NCTO), HRB Trials Methodology Research Network (HRB TMRN).

An **Infrastructure Agreement Form** must be completed for each research infrastructure and can be downloaded from GEMS. The Form must be completed, signed, dated and uploaded on GEMS. Electronic signatures are acceptable for letters/forms that are uploaded on GEMS. Please note: research infrastructures are not expected to be listed as co-applicants in applications. The word limit is **600 words.**

4. Proposal

4.1 Background to the application

Describe the background to this proposal including what is already in place to support rare disease research in Ireland, setting this clearly within the context of the Irish health research ecosystem.

1. Explain the rationale behind the establishment of this award, and the health or social care needs this is intended to address, with the size and nature of the problem in Ireland clearly communicated.
2. Provide a high-level view of rare disease research capacity in Ireland including the main centres where research is currently being undertaken, and any key research collaborations or research networks. Include high-level details on ERN membership and sites in Ireland.
3. Please give an overview of any existing salary supports and other direct financial supports provided from Hospital and Host Institution for rare disease **research**, and indicate duration of the support.
4. Please describe what is working well at present, and current challenges for undertaking rare disease research in Ireland.

The word limit is **1000 words.**

Be aware that the peer reviewers reading your application are based outside of Ireland, so it is critical to describe the healthcare delivery and rare disease research context in Ireland when discussing issues

around need (including specific needs of any under-represented groups), relevance and timeliness of the proposal.

*Project Description Figures: A file upload option is available to include an attachment to support your proposal Description. This **single document** must be uploaded on HRB GEMS. This may be images, graphs, tables as appropriate. In the same document you may also upload an organisational chart and any letters of support (other than collaborators). Figures must not be embedded within the text of the Project Description. The maximum file size is **10MB.***

4.2 Relevance of the award

Demonstrate how this proposal brings together relevant stakeholders in a single award to ensure that Ireland is better placed to engage in rare disease research activities and the planned EU Rare Diseases Partnership through a strategic use of this investment.

1. Explain how this proposal addresses the requirements of the Rare Diseases Research and Innovation Catalyst Award, in that it will boost rare disease research capacity in Ireland, including targeted support for clinical sites in Ireland as they transition to active members of the ERNs.
2. Please describe how the RDCat award will complement/leverage national or EU investments to support clinical activities associated with the ERNs, and complements recent investment in the HRB Rare Disease Clinical Trials Network.
3. Describe how this award will harness existing capabilities and collaborations in Ireland for rare disease research.
4. How will this investment address some of the challenges for rare disease research outlined in 4.1?
5. Articulate the added-value from this award above and beyond what could be achieved through individual awards. What would this research-focused HRB award enable that would not happen otherwise?

The word limit is **1200 words**.

NOTE: you are strongly advised to read the Guidance Notes and in particular the assessment criteria when writing this section.

4.3 Impact statement

The statement should be as specific as possible and provide information that reviewers will find helpful in assessing the potential impact of this 36 month HRB award. Describe expected outputs, outcomes and longer-term impacts from this investment in areas such as training and exchange opportunities for early-career researchers, generation of competitive proposals in rare disease research, greater numbers of ERN Clinical Leads engaging in research, new and enhanced research collaborations, greater involvement of patients in ePAGs and in identifying research priorities, better connectivity across the ERNs including on data infrastructures for research to boost patient focused research.

Please clearly differentiate between expected impact in a national context, and any potential impact outside Ireland.
The word limit is **800 words**.

Please refer to the Guidance Notes Section 3.1 for a description of expected outputs and outcomes.

4.4 Objectives and Deliverables

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

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

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

4.5 RD Cat Activities

Please refer to Section 3 and Section 4 of the Guidance Notes before completing this section of the application form.

In this section of the application, you are asked to describe the planned activities for the award, which will deliver the anticipated outputs and outcomes. Please explain how this spectrum of activities and supports will increase rare disease research in area of patient need.

In this section of the application you should also explain how the RD Cat leadership will reach and engage a broader community of researchers/clinicians, and how activities/supports will deliver a coordinated engagement in the planned Rare Disease Partnership

Describe any education or training opportunities planned to enhance workforce capabilities for future rare diseases research, including any activities targeted at earlier-career researchers.

The word limit is **1600 words.**

4.6 IP Considerations

The Lead Applicant together with the Host Institution has a duty to the public to ensure that discoveries and advancements in knowledge arising from any award are translated for public benefit including but not limited to commercial development of new therapies, diagnostics, materials, methodologies, and software for health[25]. Please consult with the relevant Technology Transfer Office for advice on this section, where appropriate.

The word limit is **300 words**

4.7 Gender and/or Sex Issues

A key objective of the HRB is to strive for gender balance in Irish health research. We encourage a balanced participation of genders in all research activities. Please note this section is intended to focus researchers on the **award content**, and **not** the gender balance within the team.

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

[25] 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'

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

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

If so, outline how sex and/or gender analysis will be integrated in the design, implementation, evaluation, interpretation, and dissemination as appropriate.

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

Please see Appendix IV *for resources on gender and sex considerations in research .*

The word limit is **400 words.**

4.8 Equality, Diversity and Inclusion

Please identify and explain how you will address Equality, Diversity and/or Inclusion issues within this award as relevant. Considerations may be, for example, the extent to which people you engage to develop PCOMs are representative of the patient population, the extent to which opportunities for research will include patients from minoritized communities, the level of diversity in the patient voice within the governance structures, the extent to which activities targeted at early-career researchers can be availed of by the widest pool of individuals regardless of family or socioeconomic status. The word limit is **600 words.**

Please see Appendix IV *for resources on EDI.*

4.9 Potential Safety Risks and Ethical Concerns

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

4.10 Proof of Concept (PoC) projects/Seed funding

Do you intend to use part of the HRB budget for Proof of Concept Projects/Seed Funding (Y/N)?
If Yes, please provide a description of the proposed use of seed funding for peer reviewers, including scope, nature, phasing and duration of the work, to determine the relevance and added-value in the context of this award. How much do you intend to make available for this PoC project/seed funding? Why was this proof of concept prioritised for support?

The word limit is **600 words, per proof of concept project proposed.**

Please note, any Proof of concept projects should be clearly identifiable in the Gantt chart.

4.11 Public and Patient Involvement (PPI) in this award

PPI should play a critical role in this award. This is an opportunity to attract PPI contributors to the team with a view to making the award more relevant to rare disease patients within Ireland. Also, any activities to be coordinated with the National PPI Network should be described here.

Where members of the public/patients are involved, they should be compensated for their time and contributions; this should be reflected in the project budget.

Please **describe** all public and patient involvement at each stage in the development of and throughout the award, such as, but not limited to:

- Governance and decision-making;
- development and prioritisation of work;
- contribution to work on Patient Reported Outcome Measures;
- dissemination and knowledge transfer.

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 and provide information on the individuals/groups and the ways in which they will be involved. **Please ensure to provide more detail in other sections as appropriate.**

Important: This 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.

*Please note PPI does **not** include the recruitment of study participants. Whilst this falls under patient-oriented research, it 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.*

A number of useful resources are included in Appendix IV. The word limit is **800 words**.

4.12 FAIR data management and stewardship

The HRB Policy on Research Data Management governs data gathered and generated in whole or in part from HRB-funded research from 1st of January 2020. While individual Research Data Management Plans will have to be developed for any supported proof of concept projects (if included in the award), Lead Applicants should consider how these are in line with policy requirements (of HRB and other funders). Please describe how you will work with support of data stewards or other data-related services support in the Host Institution (typically library and ICT and digital services, etc) on approaches to data management and stewardship for the award, as required. Please consider the FAIR Guiding Principles for scientific data management and stewardship: Findability, Accessibility, Interoperability, and Reusability[26]. The word limit is **600 words**

4.13 Dissemination and Knowledge Exchange Plan

Include a clear dissemination and knowledge exchange plan to indicate how the outputs from the award will be disseminated and shared and made openly accessible, in line with HRB Open Access Policy [27] . Outputs may include research articles, published patient priorities, Core Outcome Sets/PROMs/PCOMs, research data, datasets, clinical guidelines, educational resources, reports, policy

[26] 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).
[27] http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/

briefs and other relevant documents. The plan should include dissemination of results to study participants (as appropriate). Protection of Intellectual Property should be considered before data are disseminated[28]. Who are the various audiences and communities that need to be involved to maximise impact of this award?

Please note the HRB has a mandatory Open Access publication policy; demonstrate how you plan to make all publications open access. **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 **600 words**.

4.14 References

A full description of the Publications cited in the application should be provided. You can enter a maximum of 30 publications. Please enter references in the same format. For example the following format may be used:

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

For book and printed source citations:

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

5. Business Plan

5.1 Overall Aim

Please state the overall aim of the RD Cat. The word limit is **100 words**.

5.2 Business Plan

Please provide a high-level Business Plan which will deliver the strategic objectives of the RD Cat. Include details on staffing resources (to be funded by HRB and other resources) required to deliver the Work Packages), and percentage time on the job.

Provide details on communications approaches with key stakeholders, including the planned Rare Disease Partnership coordination team (e.g. individual academics/clinicians/allied health professionals, SMEs/ multinationals, cooperative groups). Please describe anticipated risks to delivery of the award during the proposed term of HRB investment and strategies to mitigate their impact.

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

The word limit is **600 words**

5.3 Work package details

Please add a small number of clearly described Work Packages which map to the relevant strategic objectives over the three year term of the HRB investment. Work Packages should have associated tasks, deliverables, and milestones. For each Work Package, deliverables will be used to monitor progress by HRB throughout the lifetime of the award if successful. Task and deliverables should be mapped against estimated completion timelines in a Gantt chart, and any milestones highlighted.

The word limit is **150 words for each Work Package description, and 200 words for the tasks and deliverables**.

Optional upload of a PERT chart which shows how the Work Packages link to the Strategic Objectives of the award.

5.4 Gantt Chart

You **must upload a Gantt chart** that lists the above Work Packages, tasks and deliverables against the estimated timelines for completion, together with any additional milestones/key dates (Figure 1).

Show key milestones for this study in the Gantt chart (2MB max). A HRB Gantt Chart Template can be found here. Please modify (change headings, add lines, extend) the document to suit your proposal.

Please note, any Proof of concept projects should be clearly identifiable in the Gantt chart.

6. Governance and Partnerships

6.1. RD Cat Management and Governance

There must be a mechanism for inclusion **of ERN Clinical Leads** and **the patient voice** in project governance structures. An International Strategic Advisory Board is suggested to provide an outside perspective to the consortium and aid with horizon scanning. In this section you must add the details of the committee.

Management and Governance

(i) Please provide a high-level description of the proposed governance structures for the award, which will fulfil the requirements of the award. Provide terms of reference for these groups, membership (where known) and proposed meeting frequency.
(ii) Describe how the overall governance structure will incorporate individual proof of concept project governance arrangements (if applicable).
(iii) Describe the approach to decision-making during the award, including the approach to strategy development. Clarify how PPI is integrated within the governance structures.

(iv) Has gender balance been taken into account at decision-making levels? (please refer to HRB's Gender Policy[29]). Does the consortium follow a Gender policy, or a broader policy on Equality, Diversity and Inclusion?

The word limit is **1000 words.**

Organisational chart

Please upload an organisational chart to illustrate proposed governance structure. Please ensure reporting lines of staff are clearly shown.

6.2 Current and Planned Collaborations and Partnerships

Provide a brief summary of your plans for the development of collaborations and partnerships with relevant stakeholders to boost rare diseases research in Ireland. Ensure the plans regarding the planned Rare Disease Partnership are clearly outlined within this. Give details of existing key collaborations and partnerships, indicating whether it is a local/regional, national or international activity for a scientific, commercial or policy and practice endeavour.

Any formal collaboration should be documented in the relevant sections of the form (Section 2.4 and 3.3 and supported by a Collaboration Agreement Form or an Infrastructure Agreement Form.) The word limit is **600 words.**

7. Budget description

The budget requested and award duration must reflect the scale and nature of the proposed activities and reviewers will thoroughly assess the level of funds and timeframe requested when reviewing the proposal.

The maximum total value of the HRB award is €3,000,000 inclusive of overhead contribution.

Overhead contributions of 30% Total direct modified costs (*excluding equipment or fees).* The apportioning of overheads should be agreed between the partner institutions during the preparation of the application. The HRB expects this to be formalised for successful applications. Please read Section 4 of the Guidance Notes on eligible costs before completing this section of the Application Form

Budgets should be broken down using the following budget headings:

1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-c):
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/.

[29] http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/gender-policy/

	Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure. **Applicants <u>should</u> include annual pay increments for staff and related costs (pension contribution, employer's PRSI contribution, and overhead contribution) in the budget.** In line with the proposed new pay agreement for State employees please apply a salary contingency of 3% from 1st October 2024 onwards. Please note this contingency should be applied cumulatively year on year. **Note:** The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators
b) Employer's PRSI	Employer's PRSI contribution is calculated at 11.05% of gross salary.
c) Employer Pension Contribution	Pension provision <u>up to a maximum of 20%</u> of gross salary will be paid to the Host Institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
2. Running Costs	For all general costs of the award, including travel and meetings costs. training, travel costs (including travel bursaries/international exchange visit costs), PPI costs, etc. Hourly costs of experts can be included here. For more substantive contributions by experts, costs should be allocated to salaries. Costs associated with provision of **seed funding** must be presented as a separate budget line. If multiple proof of concept projects are proposed, there should be a separate budget line for each. Costs associated with involving members of the **public or patients** in your network e.g. consultation workshops, PCOMs workshops, time spent reviewing material, costs of participation in advisory groups, travel expenses, honoraria, etc. should be charged to running costs. The following costs are ineligible and will not be funded: inflationary increases, cost of electronic journals.

	Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
3. Equipment	Funding for suitably justified equipment can be included in this section. **We do not expect costs in excess of €10,000 for this call.** Personal/Stand-alone computers will not be funded. All costs must be inclusive of VAT, where applicable.
4. FAIR data Management Costs	Costs related to planning in relation to data management, FAIRification, storage and archiving of research data in line with best practice of data management and stewardship and the FAIR principles **for proposed proof of concept studies, as required.** Cost of data management support calculated by hourly rates should also be included here. For more substantive contributions by data management experts, costs should be allocated to salaries. Please consult Appendix V of the Guidance Notes for examples of eligible costs.
5. Dissemination and Knowledge Exchange Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating 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[30]. Please list dissemination costs under the following categories: publications, conferences, other activities. **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) **Conferences:** We envisage that conference costs will be typically around €500 per national conference and €1,500 per international conference, per individual attending.
6.Overhead Contribution	In accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the award through an overhead payment of **30% of Total Direct Modified Costs** (TDMC excludes student fees, equipment and capital building costs). 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.

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

7.7 Budget justification and use of resources

Funding may for example be used for backfilling some sessions for the RDCat Lead, a dedicated role in coordination, or a data coordinator role, training for the consortium/early-career researchers, Research Fellows to assist with writing of grant applications, or other areas as appropriate and justified.

The HRB research-focused investment should complement national/EU investments to support clinical activities associated with the ERNs, and complement recent investment in the Rare Disease Clinical Trials Network.

(i) Please give a clear justification for each position requested, including FTE requirements, salary levels etc.[31] Please set out the proposed role in each case. Where positions are associated with clinical as well as research capacity building, please clarify that the HRB funding is being used to support research relevant activities.
(ii) HRB funded/co-funded positions should be clearly identifiable within the organisation chart in Section 6.1. Please clarify any change from existing positions as applicable (e.g. change of funding source, increased time for the role with HRB investment, new appointment planned). The HRB recognizes that given challenges in hiring, and noting the three-year duration of award, the team may wish to adapt/expand existing roles, rather than hiring additional staff.
(i) Demonstrate that HRB funding is not replacing existing financial support from the HI/Hospital/other funding partner.
(ii) Please describe how the budget requested from the HRB, plus any additional co-funding, are sufficient to successfully deliver the Work Packages. Please explain how good use is made of the budget requested, sharing resources where it is appropriate.

The word limit is **600 words.**

7.8 Upload Letter(s) of Support for co-funding

This letter, on headed paper and signed by Head of School/Research Centre/Hospital, as appropriate[32], must detail co-funding for the term of the award.

7.9 Other Funding Sources

Please indicate if you have submitted any part of this application, or a similar application, to another HRB scheme or other funding body previously. If this application has been submitted elsewhere, please indicate which HRB scheme or funding body, project title, result of submission or when outcome is expected and the amount of award.

Please note any conflicts of interest which might arise from these funding arrangements. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review.

The word limit is **200 words**.

[31] Budget as per HRB budget categories
[32] Depending on the source of the co-funding

Appendix IV: References/Useful Links

Reporting

- **COMET (Core Outcome Measures in Effectiveness Trials) Initiative**: development and application of agreed standardised sets of outcomes, known as 'core outcome sets' http://www.comet-initiative.org/
- **EQUATOR Network Library for health research reporting**: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies https://www.equator-network.org/library/
- **Registry of Research Data Repositories** http://www.re3data.org/
- **Zenodo Data Repository (OpenAIR)** https://zenodo.org/about

Evidence synthesis

- **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/

Public and Patient Involvement

- **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/
- **PPI cost calculator** http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/
- **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/
- **INVOLVE UK website for resources on Public and Patient Involvement in research** http://www.invo.org.uk
- **How to involve people in research** http://www.invo.org.uk/find-out-more/how-to-involve-people/

Sex and/or Gender issues in research

- Canadian Institutes of Health Research (CIHR) Sex and Gender definitions: https://cihr-irsc.gc.ca/e/48642.html

- **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
- **The Canadian Institute of Health Research (CIHR):** How to integrate sex and gender into research https://cihr-irsc.gc.ca/e/50836.html
- **CIHR Key considerations for the appropriate integration of sex and gender in research**: https://cihr-irsc.gc.ca/e/50835.html
- **CIHR Sex and gender research and methods:** https://cihr-irsc.gc.ca/e/49629.html
- **CIHR Online Training Modules: Integrating Sex & Gender in Health Research**: https://cihr-irsc.gc.ca/e/49347.html

Equality diversity and Inclusion in research

- **CIHR/National Sciences and Engineering Research Council (NSERC): Equity, Diversity and Inclusion considerations in the research process** https://www.nserc-crsng.gc.ca/NSERC-CRSNG/Policies-Politiques/EDI_guidance-Conseils_EDI_eng.asp#a1
- **National Sciences and Engineering Research Council: Guide for Applicants: Considering equity, diversity and inclusion in your application** https://www.nserc-crsng.gc.ca/_doc/EDI/Guide_for_Applicants_EN.pdfIn Equilibrium Equality, Diversity and Inclusion Resources: https://www.in-equilibrium.co.uk/equality-diversity-resources/
- **Health Service Executive National HR Capability and Culture Diversity Equality and Inclusion Strategy 2022-24:** https://assets.hse.ie/media/documents/Diversity_Equality_and_Inclusion_Strategy_2022-24_zPueJfn.pdf
- **National Institutes of Health Research Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project:** https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435

Data management and sharing and FAIR principles

- **Digital Curation Centre: How to develop a data management and sharing plan and sample 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)** http://www.rcuk.ac.uk/documents/documents/concordatopenresearchdata-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/

Appendix V: FAIR Data Management

Introduction

For researchers, the move to FAIR and open[33] data, where possible, means that they have the responsibility to think about what data their research will produce, how these data will be described, and how they can be made available in such a way so as to benefit science and society in general. This means that they have to draw up a data management plan (in collaboration with professionally trained colleagues) and find suitable data repositories at a very early stage of their research. FAIR principles should be applied to all research involving data and/or software creation and so be included in all data management plans (DMPs). The DMP is not be a goal in itself and should not be regarded as an additional administrative hurdle. It should instead provide an opportunity at an early stage of the research project to consider how the data generated within a project will be stored, managed and safeguarded, and thus be part of the research process from the outset. As a project progresses, the data generated may well change in type and volume, so the DMP should be seen as a dynamic framework which should be maintained and modified as the research advances.

DMP Requirements

The HRB's policy on management and sharing of research data[34] came into effect on 1st January 2020. In line with this policy, all **successful applicants will be required to submit a completed data management plan (DMP) to the HRB at the beginning of the study and a final updated version of the DMP with the final report at the end of the study.** The DMP will need to be submitted alongside a certification of approval from the designated representative(s) within the Host Institution. Successful applicants will be expected to use the HRB Data Management Plan template available through DMPOnline - https://dmponline.dcc.ac.uk/

The requirements of the HRB's DMP template can be found here https://dmponline.dcc.ac.uk/template_export/1814665590.pdf

FAIR Data Management Costs

Examples of FAIR Data Management **Costs** are listed in the table below. Costs related to management, FAIRification, storage and archiving of research data (as part of the DMP pilot the HRB is currently conducting) in line with best practice of data management and stewardship and the FAIR principles. Some of the eligible costs may include:

People	Staff time per hour for data collection, data anonymisation,
	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 (eg anonymisation)

[33] *Please note that not all FAIR data are necessarily open. Where data raises data protection or security concerns, controls and limits on data access will be required. In some cases, it will be appropriate for researchers to delay or limit access to data in order to secure intellectual property protection. Any such restrictions on access should be justified, made explicit via machine-actionable licensing and built-in accessibility protocols mechanisms.*

[34] https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-management-and-sharing-of-research-data/

Deposition and reuse	costs for depositing research data and metadata in an open access data repository
	e.g. defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please further explain
Notes	The HRB is currently not covering the cost of long-term preservation of data

Please note this list is not exhaustive and aims to provide examples only of eligible costs.