HRB Rare Diseases Research and Innovation Catalyst (RD Cat) Awards 2023

Frequently Asked Questions

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Is this call intended to fund individual rare disease research projects?

No, this call is intended to boost the capacity for rare disease research in Ireland, in particular leveraging Ireland's new membership of European Reference Networks (ERN), and ensuring that Ireland is positioned to engage with the planned European Rare Disease Partnership (RDP). Ahead of launching this targeted scheme, the HRB held an in-person Information session on Thursday 23rd February 2023 for key stakeholders in the rare disease research community, representatives from each ERN active in Ireland, as well as charity representatives and data infrastructure experts.

The purpose of the Information session was twofold:

- To provide information on the planned European Partnership in Rare Diseases and to focus on a number of relevant initiatives.
- To provide an overview of the proposed HRB call, and an opportunity for attendees to provide feedback or seek clarifications on this targeted investment.

Team

Who can apply for the HRB RD Cat Award?

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.

Will this award provide funding for individual trials or projects?

No. 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).

What are the requirements for the Lead Applicant, are Co-Lead applicants allowed?

The applicant team may designate a single Lead Applicant for the award. 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. Please see Section 5.1.1 of the guidance notes for further information on Lead Applicant eligibility.

How many Co-Applicants and Collaborators can be included in an application?

The maximum number of Co-Applicants is 10, with a maximum of 20 co-applicants and collaborators in total. It is expected that the application will have a PPI contributor as part of the team. Note: It is not mandatory to have 10 Co-Applicants, but this is to allow for flexibility should this be appropriate.

Can a Co-applicant/Collaborator be from outside Ireland?

This is possible. It is anticipated that the majority of Co-applicants/Collaborators will be based on the island of Ireland, given the aim is to boost rare disease research capacity in Ireland. However, where a researcher from outside of Ireland adds significant value they can be included as a Co-applicant/Collaborator.

What organisations could host a work package? (i.e. is this limited to academic institutions or could it include patient organisations?)

The RDCat 2023 work packages leads/co-leads are not limited to academic institutions. Patient organisations (including patient advocacy groups) could lead a work package.

Will the call expect participation from non-clinical researchers, population health, health services and social care?

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.

Expertise in the consortium could include areas such as pre-clinical and clinical research, including clinical trials, health and social care research, health economics and other fields as appropriate to the aims and objectives of the award. Ideally, existing rare disease research capabilities and collaborations in Ireland should be harnessed to ensure impact for patients.

Please refer to the scope of the award in the guidance notes when they are published.

Can a Co-Applicant receive payment for their role in the RD Cat Award?

Co-Applicants who are contract researchers may receive a salary. Researchers in contract positions/independent investigators, knowledge users[1] 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. A Host Institution Letter of Support is required for co-applicants who are contract researchers and are applying for their own salary. Please note the HRB does not fund the salary and related costs of academic staff within research institutions (including buy out from teaching time etc.) A Co-Applicant may also receive funding for items such as running costs and personnel.

Does a Co-Applicant's contract have to cover the duration of the award?

There are no requirements for the duration of a Co-Applicant's contract. However, where a Co-Applicant is applying for salary their contract must cover the duration of the award or the Host

[1] 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.

Institution must be willing to issue/extend a contract should the award be successful; this should be contained in the Co-Applicants letter of support.

Eligible Costs

What costs are covered by this award?

This award will support eligible costs **such as**, personnel costs, training, travel costs, PPI costs, , dissemination and knowledge exchange costs and overhead contributions. This list is not exhaustive: further examples are given within the Guidance notes for the scheme. Contact the HRB if you wish to check whether other activities may count as eligible costs through this award. Please see the guidance notes Section 4.1 Eligible Costs.

Is funding for registries, or data management in existing EU registries eligible?

The HRB recognises the critical importance of having a sustainable funding model and appropriate governance for patient registries[2]. In accordance with our statutory remit, HRB cannot take on the role of supporting core data requirements of the Irish healthcare system, therefore **funding of registries is not eligible**. This award should not be used to establish new registries or to subvent 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.

Creation or enhancement of an existing database to capture patients/carers interested in participating in research to boost the level of R&D may be eligible, provided there is a plan for sustainability within the HI/hospital. Support for data management/coordination may be eligible.

Optimal use of ERN registries is encouraged, and work to support connection with ERN registries for research is encouraged. Any assets created must be sustainable within the academic/healthcare system.

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.

Is buyout of clinical time possible for participants?

This is possible. 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 the writing of grant applications, or other areas as appropriate and justified.

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.

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

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.).

Is partial funding of PhD projects allowed through this award?

The RDCat 2023 award will not fund or partially fund PhD students in line with other HRB awards of this duration. 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, ICAT and Collaborative Doctoral Awards (CDA).

Can proof-of-concept pilots be supported through this award?

Yes, proof of concept pilots could potentially be funded. The selection criteria for any pilots must be determined at the time of application submission by consensus of the applicant team. Each proposed proof of concept needs to include 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. In the application form, you must describe how much you intend to make available for this PoC project/seed funding and also why this proof of concept was prioritised for support.
The PoC should be clearly identifiable in the Gantt Chart.

Is co-investment expected from a single host institution or include those hosting work packages?

An overall level of co-investment in the region of 0.5 FTE contribution to RD Cat Coordinator cost (or similar role in the award) would be welcomed as cash or in-kind. Co-investment does not need to be limited to a single host institution. HRB will count contributions from HIs, hospitals or associated charities/patient organisations as appropriate.

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 the integration of research activity into the healthcare system.

A letter/letters 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.

Could the award provide for PPI compensation?

PPI should play a critical role in this award. This is an opportunity to attract PPI contributors to the team to make 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. This may include costs such as PPI liaison, specific workshops, contributing to the development of PCOMs, travel costs for PPI contributors etc.

Is work on PROMs / PCOMs eligible for funding?

The RDCat award will allow for costs for developing or refining PROMs or PCOMs – these should be detailed under running costs. Please note, the need for the development of specific PCOMs/PROMs should be linked to gaps that are impeding research/limiting impact and any work should ensure alignment with the ongoing work of ERNs as appropriate.

Is a James Lind Alliance (JLA) approach eligible for funding?

Should a JLA approach be undertaken in the context of this award, it should be clearly justified in terms of making future research applications more relevant for patients in Ireland, more focused, and more competitive. If research priorities are identified under a JLA approach, it should be clear that there is a mechanism to take priorities forward within a funding mechanism (e.g. through the RD Partnership, HRB, other national funding, or international/philanthropic funding).

Is work to map common elements of care pathways eligible for funding?

Any work conducted on care pathways should complement and not duplicate or replace work undertaken by HSE/National Rare Disease Office and ERNs. The RDCat award is intended to boost research, so there should be a clear justification for this work in terms of being able to make e.g. future research applications more competitive.

Submission, Host Institution Signatory and the Review Process

How do I apply for the HRB RD Cat Award?

All applications must be made using the HRB online Grant E-Management System (GEMS). Applicants should carefully read the Guidance Notes prior to application.

Submission process using GEMS

Prior to final submission to the HRB, all applications must first be reviewed and approved within GEMS by the signatory approver at the research office (or equivalent) at the Host Institution. It is critical therefore that the Lead Applicant leaves 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.

How will I know that my application has been successfully submitted?

Once the HI endorses your application it will be sent automatically to the HRB to be considered for funding, a grant application number will be assigned to the application and you will receive a confirmation email.

I have submitted my application but have just realised I have amendments to make; can I amend the application?

No, once you have submitted your application, you cannot edit or retract it.

What is the review process?

The application will first be checked for eligibility by HRB staff against the minimum requirements for this scheme: that the application is in scope, eligibility of the team confirmed, as well as minimum requirements expected of the application as a whole confirmed.

The application will undergo an international **Panel** peer review process. In parallel, the application will undergo a **Public** review process. 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 recommendations of the Interview Panel will be presented for approval at the next scheduled HRB Board meeting. Please see Section 7.2 Review Process of the Guidance notes for further information.

When will awards commence?

The latest start date is December 2023.