European Joint Programme on Rare Diseases (EJP-RD)
Joint Translational Call (JTC) 2020

"Pre-clinical research to develop effective therapies for rare diseases"

Co-funded with the European Commission (EC) under the EJP-COFUND mechanism

HRB Supplementary Guidance Notes

<table>
<thead>
<tr>
<th>Key dates &amp; Times</th>
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</thead>
<tbody>
<tr>
<td>Call open</td>
<td>18 December 2019</td>
</tr>
<tr>
<td>Submission deadline for pre proposals</td>
<td>18 February 2020 (17:00 CET)</td>
</tr>
<tr>
<td>Submission deadline for invited full proposals</td>
<td>16 June 2020 (17:00 CET)</td>
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</table>

This document provides additional guidance to researchers based in the Republic of Ireland applying to this call as part of a transnational consortium. This document must be read in conjunction with the full call text and related documents (http://ejprarediseases.org/) and the FAQ on the HRB website.
European Joint Programme on Rare Diseases (EJP-RD)

Joint Translational Call (JTC) 2020

Supplementary Guidance Notes

1. Introduction

The Health Research Board and the Department of Health are partners in the European Joint Programme on Rare Diseases (EJP-RD)\(^1\).

There are at least 7000 distinct rare diseases, the great majority being of genetic origin. Although individually rare, taken together rare diseases affect at least 26-30 million people in Europe. Moreover, they represent a major issue in health care: a large number of these diseases have an early or very early onset and/or lead to a significant decrease of life expectancy. Moreover, most of them cause chronic illnesses with a large impact on quality of life and the health care system.

Therefore, research on rare diseases is needed to provide knowledge for prevention, diagnosis and better care of patients. Yet, research is hampered by lack of resources at several levels: (1) Few scientists work on any given specific disease, (2) There are few patients per disease and they are scattered over large geographic areas, causing difficulties to assemble the necessary cohorts, (3) Existing databases and bio-material collections are usually local, small, and not accessible or standardised, (4) The complex clinical phenotypes of these diseases require interdisciplinary cooperation to improve research and treatment.

The specificities of rare diseases - limited number of patients per disease, scarcity of relevant knowledge and expertise, and fragmentation of research - single them out as a distinctive domain of very high European added-value. Rare diseases are therefore a prime example of a research area that necessitates collaboration/coordination on a transnational scale.

In this context, the ERA-Net E-Rare has successfully implemented ten Joint Transnational Calls for rare disease research projects since 2006. This effort is now continued in the frame of the European Joint Programme on Rare Diseases (EJP-RD) that has been established to further help in coordinating the research efforts of
European, Associated and non-European countries in the field of rare diseases and implement the objectives of the International Rare Disease Research Consortium (IRDiRC).

A number of national and regional funding organisations will participate in the EJP RD Joint Transnational Call (JTC) 2020 and will fund multilateral research projects on rare diseases together with the European Commission (EC) under the EJP-COFUND action. The Health Research Board will support participation of researchers from the Republic of Ireland within the 2020 transnational joint call.

2. **Aim**

The aim of the call is to enable scientists in different countries to build an effective collaboration on a common interdisciplinary research project based on complementarities and sharing of expertise, with a clear future benefit for patients.

3. **Scope**

The research topic is “Preclinical research to develop effective therapies for rare diseases.”

Transnational research proposals must cover at least one of the following areas, which are equal in relevance for this call:

**Research proposals must cover at least one of the following areas:**

1. Development of novel therapies in a preclinical setting (including small molecules, repurposing drugs, cell and gene advanced therapies) focusing on condition(s) with unmet medical needs;
2. Use of disease models suitable for medicinal product’s development according to EMA guidelines;
3. Development of predictive and pharmacodynamics (PD) biomarkers (with appropriate analytical methods e.g. OMICS) in a preclinical setting (e.g. in the validated model or in pre-collected human samples) for monitoring the efficiency of the therapy. The model chosen must mimic the human diseases and be transposable so that the biomarker identified in animals can be valid for humans;
4. Proof of principle studies fostering an early (pre-clinical) stage of drug development (excluding interventional clinical trials of phase 1-4).

The following approaches and topics are excluded from the scope of the call:

- a) Therapeutic approaches concerning rare infectious diseases, rare cancers and rare adverse drug events in treatments of common diseases;
- b) Interventional clinical trials;
- c) Surgery or radiation therapies;
- d) Studies that focus on research to accelerate diagnosis or to set up new registry/cohort studies to explore disease progression and mechanisms as these were the focus of JTC 2019;
- e) Rare neurodegenerative diseases which are within the main focus of the Joint Programming Initiative on Neurodegenerative Disease Research (JPND; http://www.neurodegenerationresearch.eu/). These are: Alzheimer’s disease and other dementias; Parkinson’s disease (PD) and PD-related disorders; Prion disease; Motor Neuron Diseases; Huntington’s disease; Spinal Muscular Atrophy and dominant forms of Spinocerebellar Ataxia. Interested researchers should refer to the relevant JPND calls.
**Childhood dementias/neurodegenerative diseases are not excluded.**

Projects shall involve a group of rare diseases or a single rare disease following the European definition i.e. a disease affecting not more than **five in 10,000 persons** in the European Community, EC associated states and Canada. Applicants are encouraged to assemble groups of rare diseases based on solid criteria and commonalities if this leverages added value in sharing resources or expertise and has the capacity to elucidate common disease mechanisms and therapeutic targets.

Translatability into humans should be one of the key focuses of the project, and applicants should demonstrate access to relevant scientific or regulatory expertise (e.g. through innovation task forces or competent national authorities).

### 4. Eligibility of a Lead Applicant (Partner) from the Republic of Ireland

A Lead Applicant must

1. be from an HRB approved host institution in the Republic of Ireland (RoI). For a list of approved Host Institutions and further information see: [http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/](http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/).

2. hold a post (permanent or a contract that covers the duration of the award) as an independent investigator;

   or

   be an individual who will be recognised by the Host Institution upon receipt of the HRB award as a contract researcher as defined above. A Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

3. Show appropriate evidence of expertise matched to the nature and context of the project;

4. Show evidence of achievement as an independent researcher in their chosen research field by:

   a) Demonstrating a record of research output, with at least **three** publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs such as published book chapters, reports to government and/or any other relevant outputs that have resulted in a significant impact in their field.

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

5. Show evidence that they possess the capability and authority to mentor, manage and supervise less experienced researchers and to manage relationships with co-applicants, collaborators and the host institution.
Please note:

- The Lead Applicant cannot request his/her own salary
- Any named co-applicants cannot request their own salary

All proposals with researchers from the Republic of Ireland will be subject to a HRB check following submission to the centrally coordinated peer review to ensure eligibility against the above criteria.

5. Funding and Duration

Whilst joint applications will be submitted involving groups from different countries, individual research groups in successful projects will be funded by the participating EJPRD JTC 2020 funding organisation(s) within their country. The maximum amount that funders in each participating country will contribute to their successful applicants can be found in the call text.

The maximum duration of a project is **36 months**.

### Irish partner(s)

For successful applications involving applicants based in HRB recognised host institutions in the Republic of Ireland, the total funding available will be a **maximum of €370,000 over 36 months** (inclusive of overheads and pension contributions). It is expected that the HRB will fund one or two awards depending on the funding requested from applications with Irish partner(s).

Eligible costs are:

- Personnel
  - Salary-related costs for research personnel
  - Stipends and fees
- Small equipment costs
- Direct running costs (either other direct costs, or consumables) – which may also include FAIR data management costs and travel
- Dissemination and knowledge exchange costs (under other direct costs)
- Overheads contribution

Please refer to Appendix I for further details of eligible costs under HRB regulations.

6. Host institution

The Host Institution for the Irish partner(s) must be a HRB approved Host Institutions (see [http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/](http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/)) and be nominated by the Irish partner. The Host Institution for the award is the body in charge of the financial and administrative co-ordination of the Irish component of the research collaboration receiving a research grant from the HRB.
7. Application and Assessment process

Research project consortia who intend to submit a transnational proposal should register as soon as possible under, by clicking on “sign up” and follow further instructions.

There will be a **two-stage** application process:

- pre-proposals and
- invited full proposals

In each case, a single proposal document (in English) shall be prepared by the partners of a joint transnational proposal and must be submitted to the Joint Call Secretariat by the coordinator. Each transnational project team submitting a proposal must nominate one PI to act as coordinator. The coordinator will submit a single **application** via the electronic submission system on the following site.

1. A **pre-proposal submission form** must be used when submitting the application. This proposal template can be downloaded from the [www.ejprarediseases.org](http://www.ejprarediseases.org) website, along with the call text (detailing the aim and scope of the call, eligibility and submission details, the evaluation process and assessment criteria, reporting requirements) and the guidance for applicants. **These documents must be consulted in addition to the HRB Supplementary Guidance Notes and HRB Frequently Asked Questions and Ireland country-specific summary requirements documents on the HRB website.**

   **Irish partner(s)**
   
   Before applying Irish partner(s) from the Republic of Ireland are strongly advised to check eligibility as partner(s) of the consortium.

   Eligible pre-proposals will be reviewed via a written (remote) peer review process. The reviewers will assess the pre-proposals and complete a written evaluation form with scores and comments for each criterion. The Call Steering Committee members (funders) will meet to decide which proposals will be invited for the full-proposal submission based on the reviewers’ recommendations and to ensure a reasonable balance of requested and available national/regional budgets.

2. By late April 2020, the coordinators of the top-ranked proposals will be invited by the Joint Call Secretariat to submit a **full proposal** no later than June 16, 2020 17.00 CEST.
   
   Full details on the evaluation process and assessment criteria are contained within the **call text**.

   **Irish partner(s)**
   
   Irish partner(s) in a consortium must also provide a copy of the submitted full proposal to the HRB following submission to the European Portal. In addition, Irish applicants must also include justification for their requested budget, and clarification on deliverables assigned to the partner from Ireland. A template requesting the information required from applicants from Ireland will be provided by the HRB.
8. **Timeframe**

The expected timeframe for this call for proposal is as follows:

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>18 February 2020</td>
<td>Pre-proposal submission deadline</td>
</tr>
<tr>
<td>End April 2020</td>
<td>Outcome and invitation to full proposal</td>
</tr>
<tr>
<td>16th June 2020</td>
<td>Full proposal submission deadline</td>
</tr>
<tr>
<td>28th July 2020</td>
<td>Deadline for rebuttals</td>
</tr>
<tr>
<td>November 2020</td>
<td>Notification of funding decision</td>
</tr>
</tbody>
</table>

9. **Contacts for further information**

For general enquiries on this call, the Joint Call Secretariat ANR, France for this call can be contacted at: [EJPRDcall@anr.fr](mailto:EJPRDcall@anr.fr)

**Florence Guillot**

florence.guillot@agencerecherche.fr
+33 (0) 1 78 09 80 01

**Kiri Couchman**

kiri.couchman@agencerecherche.fr
+33 (0) 1 78 09 81 29

For specific enquiries from applicants from the Republic of Ireland to this call, contact:

**Louise Drudy**

Project officer
Research Strategy and Funding
Health Research Board
ldrudy@hrb.ie

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB’s procedure for appealing funding decisions is available at [http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/](http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/).

In view of the overwhelming evidence that both active and passive smoking of tobacco are injurious to health, the HRB is unwilling to fund applications from individuals applying for, holding, or employed under a research grant from the tobacco industry. The HRB cannot fund research using human embryonic stem cells or tissues, or intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
Appendix I - HRB Budget

The Irish component of the budget for the project must **not exceed €370k** (including overheads and pension contributions).

At full application stage, if invited, you will be providing a summary and justification of the costs and duration associated with the project. **There is no set limit per annum** therefore the proposed budget per annum should reflect anticipated annual costs.

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

<table>
<thead>
<tr>
<th>1. Personnel costs</th>
<th>Must be listed for each salaried personnel under each of the following subheadings (a-c):</th>
</tr>
</thead>
</table>
| 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/](http://www.iua.ie/research-innovation/researcher-salary-scales/)  
Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure.  
Salaried researchers who are registered for a PhD degree (e.g. clinical fellows) are expected to have a contribution to gross salary costs (inclusive of employee’s pension contribution) up to a maximum amount of Level 3, Point 1 of the most up to date IUA scale.  
Applicants are advised that public sector pay increases for the period until end of 2020 have been agreed. Please find new pay scales at [https://www.iua.ie/research-innovation/researcher-salary-scales/](https://www.iua.ie/research-innovation/researcher-salary-scales/) If your application stretches beyond 2020; please apply a salary contingency of 2.5% p.a.  
**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 up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution.

If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference.

Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.

d) Student Stipend

The HRB student stipend is €18,000 per annum (tax exempt).

e) Student Fees

Fees for students registered for a higher degree at EU level only. Applicants should liaise with their Host Institution’s Research Office for fee levels. **Annual increments are not provided within budget.**

2. Running Costs

For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs etc.

Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, Clinical Research Facilities support, MRI facilities etc. will be considered under running costs.

**Travel costs** associated with running the project should be included and justified under the “running costs” budget line. Other travel costs may be under dissemination costs.

Costs associated with involving members of the **public or patients** in your research e.g. consultation workshops, costs of participation in advisory groups, travel expenses, honoraria, etc. should be charged to running costs.

The following costs are ineligible and will not be funded: training courses/workshops with the exception of training in public and patient involvement in research, inflationary
increases, cost of electronic journals.

**Note:** Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.

### 3. Equipment

Funding for suitably justified equipment can be included in this section. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e. overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified. All costs must be inclusive of VAT, where applicable.

### 4. Dissemination Costs

Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[^2]. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary.)

Where appropriate please ensure that the dissemination budget line includes the call requirement of “participation of the Irish partner leaders at an intermediate and/or a final status symposium to present the results of their projects (organized by the Joint Call Secretariat).”

**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](http://www.hrbopenresearch.org)) free of charge.

**Conferences:** We envisage that conference costs will be typically around €500/year for national conference and €1,500/year for international conference.

### 5. FAIR Data Management Costs

Costs related to data management, FAIRification process, storage and archiving of research data in line with best practice of data management and stewardship and the FAIR principles **incurred during the lifetime of the award** should be included. Hourly rate for data management support may be also included here.

The HRB will not cover any costs for long term preservation.

6. Overhead Contribution

In accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for laboratory or clinically based research and 25% of Total Direct Modified Costs for desk-based research.

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

Example of budget details

**Budget requested (for the research conducted by researchers from Ireland)**

Please copy/paste additional positions as required

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tbody>
<tr>
<td><strong>Position 1 Basic Salary</strong></td>
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<tr>
<td><strong>Position 1 Employer Pension Contributions</strong></td>
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<td><strong>Position 1 Employers PRSI</strong></td>
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<tr>
<td><strong>Position 2 Basic Salary</strong></td>
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<tr>
<td><strong>Position 2 Employer Pension Contributions</strong></td>
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<td><strong>Position 2 Employers PRSI</strong></td>
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<tr>
<td><strong>Stipend</strong></td>
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<td><strong>Student Fees</strong></td>
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<tr>
<td><strong>Equipment</strong></td>
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<tr>
<td><strong>Running costs (including project related travel)</strong></td>
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<tr>
<td><strong>FAIR Data management costs</strong></td>
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<tr>
<td><strong>Dissemination and knowledge exchange costs (including dissemination-related travel)</strong></td>
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<tr>
<td><strong>Overhead Contribution</strong></td>
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<tr>
<td><strong>Sub total</strong></td>
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</table>

Total requested: €

**Budget Justification (for the research conducted by researchers from Ireland)**

- **Personnel costs** must specify level and point on scale, and which work package they will contribute to.
- **Travel costs**: Where appropriate please ensure that the dissemination budget line includes the call requirement of “participation of the coordinators and/or national partner leaders at an intermediate and/or a final status symposium to present the results of their projects (organized by the Joint Call

3 http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-usage-of-research-overheads/
Secretariat).” Other travel costs associated with running the project should be included and justified under the “HRB running costs” budget line.
## Appendix II - Call documents and useful links

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<tr>
<td>• Call text</td>
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<tr>
<td>• Guidelines for Applicants (including country-specific eligibility requirements)</td>
<td></td>
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<tr>
<td>• Proposal template (submissions must use this template)</td>
<td></td>
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<tr>
<td>• FAQ</td>
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<tr>
<td>• Contact details for Call Secretariat</td>
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<tr>
<td>EJP RD website</td>
<td><a href="http://www.ejprarediseases.org">http://www.ejprarediseases.org</a></td>
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## Appendix I - Health Research Board (HRB), Ireland: specific regulations

<table>
<thead>
<tr>
<th>Country / Region</th>
<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding organisation</td>
<td>Health Research Board</td>
</tr>
<tr>
<td>National contact person</td>
<td>Dr Louise Drudy, <a href="mailto:ldrudy@hrb.ie">ldrudy@hrb.ie</a></td>
</tr>
<tr>
<td>Funding commitment</td>
<td>Up to €370,000 in total</td>
</tr>
<tr>
<td>Anticipated number of fundable research partners</td>
<td>Up to two</td>
</tr>
<tr>
<td>Maximum funding per grant awarded to a partner</td>
<td>The maximum funding available for this call is €370,000. It is expected that the HRB will make one or two awards</td>
</tr>
<tr>
<td>Eligibility of project duration</td>
<td>Up to 3 years</td>
</tr>
</tbody>
</table>

### Eligibility of principal investigator or other research team member

The Lead Applicant (Partner) must:

1. Hold a post (permanent or a contract that covers the duration of the award) in a recognised research institution in the Republic of Ireland (the “Host Institution”) as an independent investigator, or
2. Be a contract researcher recognised by the Host institution as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible, or
3. Be an individual who will be recognised by the Host Institution upon receipt of the HRB ILP award as a contract researcher as defined above. The Lead applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

The Lead Applicant will:

6. Show appropriate evidence of expertise matched to the nature and context of the project;
7. Show evidence of achievement as an independent researcher in their chosen research field by:
8. Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs such as published book chapters, reports to government and/or any other relevant outputs that have resulted in a significant impact in their field.
9. 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.

10. Show evidence that they possess the capability and authority to mentor, manage and supervise less experienced researchers and to manage relationships with co-applicants, collaborators and the host institution.

11. The Lead Applicant cannot request his/her own salary.

12. Any named co-applicants cannot request their own salary.

### Eligibility of costs and types

Funding available is inclusive of overheads and pension contributions:

- Personnel
  - Salary-related costs for research personnel
  - Stipends and fees
- Small equipment costs
- Direct running costs *(either other direct costs, or consumables) – which may also include FAIR data management costs and travel*
- Dissemination and knowledge exchange costs *(under other direct costs)*
- Overheads contribution

In accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for **laboratory or clinically-based research** and 25% of Total Direct Modified Costs if **desk-based research**.

### Submission of other information at the national level

Participants in consortia from Institutions in Ireland are asked also to provide a copy of the submitted full proposal to the HRB following submission to the European Portal. In addition, applicants will be requested to submit the **deliverables and supplementary budget information** for the partner(s) from Ireland. This will expedite contract negotiations with HRB in the case of successful consortia with applicants from Ireland. A template requesting this further information required from applicants from Ireland will be provided by the HRB at full proposal stage.

### Submission of financial and scientific reports at the national level

- Annually