COVID-19 Pandemic
Rapid Response Funding Opportunity (COV19) 2020

Guidance Notes

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<td>Application Open</td>
<td>26 March 2020</td>
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<td>Application Closing Date</td>
<td>09 April 2020 @ 13:00</td>
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Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) [https://grants.hrb.ie](https://grants.hrb.ie), and this system will close automatically at the stated deadline and timeline listed above.
COVID-19 Pandemic
Rapid Response Funding Opportunity (COV19) 2020

Update 1 April 2020

The HRB’s rapid response call is not designed to support clinical trials involving investigational medicinal products (IMPs). However, the HRB recognises the importance of high-quality clinical trials to inform our understanding of the treatment, diagnosis and prevention of COVID-19. In addition, considering availability of IMP and pressures on clinical staff time, it is important that Ireland takes a strategic, national approach to the selection of trials. For this reason, the Expert Advisory Group (EAG) to the National Public Health Emergency Team (NPHET) has established a Research Subgroup to take a more coordinated, national approach to COVID-19 trials.

The Research Subgroup is currently considering the criteria against which to assess the appropriateness of clinical trials. These criteria may include:

- Potential for equitable establishment of the trial nationally
- Availability of the medications (nationally and/or centrally provided by an international trial)
- Whether the trial is a platform study and capable of adopting new interventions in response to emerging evidence
- The degree to which the trial has the potential to impact on clinical care in the context of the pandemic
- The degree to which the trial can add to or extend the evidence base
- The degree to which Irish investigators are believed to be in equipoise regarding the therapeutic alternatives within the trial
- For placebo or untreated trial arms, the extent to which the standard of clinical care proposed by the trial conforms with current best practice in clinical care of COVID-19 in Ireland.

Three large national trials are either underway or under consideration:

1. The REMAP Cap trial mobilises rapid support for a COVID-19 clinical trial among Irish patients in Intensive Care Units as part of global research efforts to tackle the pandemic. The trial will start enrolling COVID-19 patients on the island of Ireland at the start of April and will test interventions for COVID-19 in critically ill patients, capture the outcomes and analyse data across an international network in a global effort to reduce the impact of COVID-19 in Intensive care settings. In Ireland, the trial is led by Professor Alistair Nichol.
2. The NPHET has accepted a recommendation from the Research Sub-Group that Ireland participate in the WHO SOLIDARITY trial, which will compare the safety and effectiveness of four different drugs or drug combinations against COVID-19 in hospitalised patients who are moderately ill. To date, more than 45 countries are contributing to the trial.

3. The potential for Ireland to engage in a community-based trial led by the University of Oxford is currently under review.

The practical implementation of this approach is evolving. The HRB is working on this and will communicate a mechanism shortly.
1. Introduction
On 31 December 2019, the World Health Organization (WHO) was informed of a cluster of cases of pneumonia without known cause detected in Wuhan City, in the Hubei Province of China. On 7 January 2020, the Chinese authorities identified this to be a previously unknown type of coronavirus subsequently named SARS-CoV-2, and the linked illness named COVID-19. On 11 March 2020, the WHO Director-General declared the outbreak a pandemic, with new cases identified daily. Consult the WHO operations dashboard1 for the most up-to-date information.

The Health Research Board (HRB) and Irish Research Council (IRC) are launching a joint rapid response funding opportunity supporting a coordinated global research response to COVID-19. The research priorities of the HRB-IRC call are aligned with the WHO R&D Blueprint2 and the Irish COVID-19 Government Action Plan3. They are informed by the Global Infectious Disease Collaboration for International Disease Preparedness (GloPID-R) and the Coalition for Epidemic Preparedness Innovations (CEPI). Along with over 100 other international organisations HRB has signed a Joint statement on sharing research data and findings relevant to the novel coronavirus (COVID-19) outbreak4. Initiated by Wellcome, the statement ensures the WHO and others have rapid access to emerging findings that would aid the global response.

This call is closely co-ordinated with the rapid response call launched by Science Foundation Ireland (SFI), Enterprise Ireland (EI), and IDA. The SFI, EI and IDA call is an agile and adaptive initiative to support development of innovative solutions (including STEM-based, social/behavioural science) that can have rapid demonstrable impact on the current COVID-19 crisis in Ireland.

Applicants are advised to consider best fit with either instrument. The funders will continue to coordinate activities relevant to COVID-19.

A range of research is needed to effectively mitigate the rapid spread of COVID-19 and minimise its direct and indirect impacts on individuals and communities. Development of effective countermeasures also requires a coherent and integrated response from researchers, public health authorities, industry, policy makers, the healthcare system and the public. As such, projects funded through this call are encouraged to build on existing networks, infrastructures and relationships with partners in Ireland and internationally.

HRB and IRC will also play a co-ordination role, liaising closely with other funders and Government Departments in the national system to expedite support of proposals outside this scope.

2. Objectives
In response to the fast evolving COVID-19 pandemic, the HRB, in cooperation with the IRC, is launching a rapid response mechanism to fund research that will provide evidence for the national and global efforts to deal with the virus outbreak.

1 https://experience.arcgis.com/experience/685d0ace521648f8a5b3eeee1b9125cd
2 https://www.who.int/blueprint/priority-diseases/key-action/Roadmap-version-FINAL-for-WEB.pdf?ua=1
Expedited timelines apply throughout the process. It is expected that contracting and start-up of successful projects will be equally expedited, and that project staff will mostly be redeployed rather than specifically recruited. Host Institutions are required to treat awards arising from the call with utmost urgency.

3. Scope

The scope of this funding call covers medical countermeasures, health service readiness, and social and policy countermeasures to COVID-19. HRB may fund awards under any of these headings whilst the IRC will fund a number of awards under the social and policy countermeasure strand.

The duration of awards is between 3 and 24 months, and deliverables should emerge as early as possible. Projects of immediate relevance will be prioritised over those with longer-term outlook.

All deliverables must be reported in real time in open access formats and shared with the relevant stakeholders.

Examples of research in scope include:

Medical countermeasures (awards supported by HRB)
- Natural history, transmission and diagnostics
- Virus origin and management measure at the human animal interface
- Epidemiological studies
- Clinical management
- Infection prevention and control, including health worker protection

Health service readiness (awards supported by HRB)
- Care pathways
- Workforce deployment and planning, including balancing pandemic needs with ongoing needs of the health and social care system
- Technology and data to improve efficiency
- Tailoring the public health response to the unique circumstances of different populations
- Logistics of the response (e.g. infrastructure, transport, evaluation) and opportunities for their immediate improvement

Social and policy countermeasures (awards supported by the IRC)
- Public health response, including the feasibility and effectiveness of social policies aiming to prevent and contain COVID-19 and to mitigate its secondary impacts (e.g. supply shortages, school closures, travel restrictions, quarantines, racism);
- Supporting the psychosocial needs of those caring for people with COVID-19;
- Strategies to combat misinformation, stigma, and fear, to address their underlying drivers, and to improve public awareness, knowledge, and trust during the outbreak response;
- Involving local perspectives, citizens, and communities in the outbreak response effort;
- Social dynamics of transmission and vulnerability and how to best communicate related risks, uncertainties, and implications;
- Dynamics/impacts in respect of socio-economically disadvantaged or marginalised groups.

There will be no strict scope check for this call as long as relevance to the COVID-19 outbreak is proven.
4. Funding
Funding available is typically up to €200,000 per project including overheads contribution. In exceptional circumstances and where well justified funding awards may be higher.

5. Format of applications
The format of applications is based on shortened version a well-established HRB funding instrument, the Investigator-Led Projects. However, whilst not a requirement we emphasise that applications with involvement of health and care practitioners, policy makers and planners are particularly welcome. Applications may be made on an all-island basis. We encourage researchers to address questions of relevance to the National Public Health Emergency Team\(^5\), the Health Protection Surveillance Centre\(^6\), and relevant groups within the HSE and internationally.

Please find detailed guidance on the application form in Appendix 1, and a list of useful links in Appendix 2.

6. Eligibility criteria of Lead Applicant, Co-Applicants and Collaborators

a. Lead Applicant

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

The Lead Applicant must be an independent investigator based in a recognised host institution in the Republic of Ireland:

- 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
- 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 he/she will be fully responsible.

The Lead Applicant must demonstrate that they have the skills, knowledge and support necessary to direct the proposed research and to be actively engaged in carrying the research through to completion. This means that the LA will show appropriate evidence of expertise matched to the nature and context of the project

*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.*


\(^6\) https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/
b. Co-Applicants

A Co-Applicant has a well-defined, critical and substantial role in the conduct and steering of the proposed research. Co-Applicants from outside of the Republic of Ireland are welcome. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards his/her own salary if they are in salaried positions. However, Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to the research project, for the duration of the award if they are contract independent investigators (up to a maximum of 5 Co-Applicants can be listed).

c. Collaborators

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

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

To expedite the process, Collaboration Agreement Forms from each official collaborator will be requested during contracting and not as part of the application. Forms will be made available during the process and given a very tight timeline for contact negotiation it is recommended that Lead Applicants collate these documents as soon as possible.

d. Funded Personnel

Given the very tight timeframe for this funding call, it is expected that most funded personnel will be redeployed from other research projects. Please identify available staff immediately.

7. Host Institution

A HRB Host Institution⁷ is a research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under this award scheme. 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 website⁷.

⁷ http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/
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.

8. Access and support from research infrastructure
Applications availing of the advice, research design, data management services and/or other forms of support from a Clinical Research Facility/Centre (CRF/CRC), other infrastructure (e.g. Centre for Applied Medical Imaging, CAMI, Centre for Support and Training in Analysis and Research (CSTAR) or a biobank) are required to provide additional information detailing the scope and nature of the engagement (this includes national and international facilities, Units and networks where justified).

To expedite the process, Infrastructure Support Forms will be requested during contracting and not as part of the application. Forms will be made available during the process and given the very tight timeline for contact negotiation it is recommended that Lead Applicants collate these documents as soon as possible.

9. Data Sharing and Management
Rapid data sharing is the basis for public health action. Data produced as a result of this funding must be shared in line with
- The principles set out in the Joint statement on sharing research data and findings relevant to the novel coronavirus (COVID-19) outbreak8 and
- The principles to make research data FAIR (Findable, Accessible, Interoperable and Re-usable)9, thereby increasing the re-use of data and promoting transparency and accountability.

The HRB’s policy on management and sharing of research data10 came into effect on 1st January 2020. In line with this policy, all successful applicants are required to submit a completed data management plan (DMP) to the HRB 3 months after the confirmed start date of the project and a final updated version of the DMP with the final report at the end of the project. The DMP will need to be submitted alongside certification of approval from the designated representative(s) within the Host Institution. Successful applicants are requested 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

HRB Open Research is a 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). It is a fast way of sharing data and ensuring citations for underlying data sources. HRB strongly encourage grant holders to use this platform to publish all research outputs including study protocols, registered reports, case studies, data notes, etc. All publications are indexed in PubMed.

9 https://www.go-fair.org/fair-principles/
10 https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-management-and-sharing-of-research-data/
10. Public and Patient Involvement (PPI) in research

'Public and patient involvement' represents an active partnership between members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research.

In general, the HRB and IRC promote the active involvement of members of the public in the research that we fund. However, we appreciate that PPI takes time, and that it might be more relevant to some potential projects under this call than to others. We expect that only a limited number of applications will include PPI elements. There will be no public review of applications under this scheme.

11. General Data Protection Regulation

The General Data Protection Regulation (GDPR) came into force on 25 May 2018. As a result the applicant team will be asked through GEMS to consent that personal data provided as part of this application, including but not limited to CV information, may be shared with person(s) based outside of the European Economic Area (EEA) for the specific purpose of obtaining peer reviews of this application. International reviewers play a vital role for the HRB and IRC in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Individual peer reviewers are selected for their specific expertise in relation to submitted applications and can be based anywhere in the world.

Furthermore, by confirming participation, you will be asked to consent that the HRB and IRC use the information you provide (regarding all applicant team members) to consider your application, to contact you about your application, and if you are successful, to manage your grant throughout its lifetime in accordance with HRB general T&C for research awards. This will include contacting you with regard to monitoring of progress through written reporting and other means e.g. interim review. We will publish some basic information on successful awards including PI, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended, we will continue to keep your information on file (in accordance with HRB and IRC policies) to allow us to evaluate the outcomes, outputs and impacts of our investment in your research.

Please note that we will also use information associated with unsuccessful applications for a number of the purposes outlined above such as generating general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment e.g. demographics of applicants, research areas of applicants. Similarly, we will use the information provided about people employed on awards to help evaluate our career support and capacity building initiatives.

12. Application and review process

The HRB and IRC are committed to an open and competitive process underpinned by international peer review. Applications will be initially checked for eligibility. To expedite the process the review will be completed in a single step by a panel of international reviewers with a view to making funding recommendations. The panel will meet virtually and will make a recommendation to the HRB/IRC at the end of the meeting. The Board of the HRB will approve the funding recommendation.

The exact number funded per Panel will be determined by the quality of applications and available budget. The Panel members will evaluate all applications based on the following assessment criteria.

a. Assessment criteria
Assessment criteria are weighted equally. Successful applications are likely to score well in all criteria.

1. Potential impact:
   - Potential to contribute to the global or national response to COVID-19 with regards to patients, public and/or healthcare systems
   - Timeliness of research outputs
   - Planned knowledge dissemination and translation including rapid data sharing

2. Quality of research project:
   - Appropriateness of the proposed design and methodology
   - Appropriateness of the budget and justification for amount requested

3. Quality of team:
   - Track record of team members in fields related to proposed research
   - Ability of the project team to carry out the proposed research
   - Ability of team to quickly mobilize necessary resources

In case of equal ranking projects with high potential impact will be prioritised.

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

Reviewers are required to respect the confidentiality of the peer review process, which is designed to protect and preserve the integrity of the HRB’s advisers and processes. Reviewers may not discuss any aspect of the scoring or assessment with applicants or colleagues. All such requests must be referred to the HRB.

13. Timeframe
Given the rapid nature of the process exact dates cannot be confirmed yet. However, the table below sets out our ambition to enable research projects to commence as soon as possible. We recognise that this will require an extremely timely turnaround by the Host Institution at a time of disruption. However, given the circumstance of the fast-growing impact of COVID-19 we consider this to be appropriate.

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<td>26 March 2020</td>
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<td>9 April 2020, 13:00</td>
<td>Call closing for applications to all panels</td>
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<td>Approx. 20 April 2020</td>
<td>Panel decision</td>
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<td>Board approval</td>
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<tr>
<td>29-30 April 2020</td>
<td>Contract and follow up supporting documentation completed</td>
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<tr>
<td>From 11 May 2020 asap</td>
<td>Expected start dates of projects</td>
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14. Contact
For further information on the COV19 2020 contact:
Dr Annalisa Montesanti
Programme Manager

COVIDcall@hrb.ie

Please also refer to frequently asked questions on the HRB website.

*The HRB and IRC reserve the right to reject any application that does not meet the terms of this call.*
Appendix 1: 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 and IRC, 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, which can then be jointly edited 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’.

Lead Applicants will be asked to go through a check list of mandatory Yes/No questions. In order to start the application, the Lead Applicant must satisfy the conditions of this check list.

The Lead Applicant will be then able to start the application. Further details for completing each of the main sections of the application form are provided below:

Lead Applicant’s Consent to share personal data in application
I consent that personal data provided as part of this application, including but not limited to CV information, may be shared with person(s) based outside of the European Economic Area (EEA) for the specific purpose of obtaining peer reviews of this application. Y/N

Host Institution
A HRB Host Institution is a research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all of the HRB’s 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. Approved HRB Host Institutions are listed on our website12. Information is available on the same webpage on the application process for research performing organisations to be approved as HRB Host Institutions.

In GEMS you will be asked to identify a Host Institution (from this list) and type it 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 COV19-ILP. The signatory’s details are pre-populated in the system so the applicant just needs to click ‘NOTIFY’ within GEMS. We recommend

12 http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/
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 LA and if they have any queries or clarifications they can engage directly to resolve them with the LA. 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 and IRC.

1. Project Details

1.1 Project Title
This should be descriptive and concise and should reflect the aim of the project.

1.2 Project Duration
Please indicate the expected length of the proposed project in months (between 3 and 24 months) and the proposed start date.

1.3 Project Abstract
This should be a succinct summary of the proposed research question. The aims and hypotheses of the project should be conveyed with clarity. The objectives of the project and what the work is expected to establish should be described. Ideally it provides a clear synopsis of your proposal and should set the research proposal in context. The word limit is 300 words.

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

2. Project Description
Please ensure that your application is focused and that sufficient evidence is provided to enable the international panel members to reach a considered judgement as to the quality of your research proposal, its relevance to objectives of the call and its immediate impact. Some sections are not mandatory.

2.1 Scope
Please select the broad research area of your project:
- Medical countermeasures
- Health services readiness
- Social and policy countermeasures

2.2 Research Question
Clearly state the research question behind the proposed work. The word limit is 50 words.

2.3 Project overview
Please provide an overview of the project addressing:
   a) Potential to contribute to the global or national response to COVID-19 with regards to patients, public and/or healthcare systems;
   b) Timelines of research outputs;
   c) Study design, approach and methodology including any PPI;
   d) Ability of team to quickly mobilize necessary resources.
The word limit is 1000 words.

2.4 References
A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of 15 publications. Please enter references in the same format. For example the following format may be used:


For book and printed source citations:

2.5 IP Considerations (where relevant)
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 health13. Please consult with the relevant Technology Transfer Office for advice on this section, where appropriate.

Please describe any current Intellectual property (IP) that will be relevant for the project and whether such IP assets are held by the applicants, and/or others outside the research team. Such IP might include software, checklists, scales, protocols, guidelines, questionnaires, or medicinal products for example. Has relevant background IP for your project been identified? If IP is required is there freedom to operate, such that this research can eventually be translated. What arrangements are in place to manage IP during the project, and ensure it is protected (if appropriate) prior to dissemination? Do you foresee any barriers to use of IP in order for the research outputs to be adopted? The word limit is 100 words.

2.6 Dissemination, knowledge exchange and data sharing plan
All outputs must be reported in real time in open access formats and shared with the relevant stakeholders in line with the Joint statement on sharing research data and findings relevant to the novel coronavirus (COVID-19) outbreak. The HRB expect study protocols to be published on the HRB open research before at the start of the research project.

Summarise

- A clear dissemination and knowledge exchange plan to indicate how the research outputs you anticipate producing during and after your project will be disseminated, translated and shared, in particular if and how you are working with stakeholders.
- The approach to data sharing during and at completion of the award and how you will seek to ensure that stakeholders such as the World Health Organization (WHO), the National Public Health Emergency Team14, the Health Protection Surveillance Centre15, have rapid access to emerging findings that could aid the global and/or national response.

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15 https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/
Protection of Intellectual Property should be considered before data are disseminated\(^6\).

The word limit is **300 words**.

**Notes:**

- Please note the HRB’s policy on management and sharing of research data\(^7\) came into effect on 1st January 2020. In line with this policy, all successful applicants are required to submit a completed data management plan (DMP) to the HRB **3 months after the confirmed start date** of the project and a final updated version of the DMP with the final report at the end of the project. The DMP will need to be submitted alongside certification of approval from the designated representative(s) within the Host Institution. Successful applicants are requested to use the HRB Data Management Plan template available through DMPOnline - [https://dmponline.dcc.ac.uk/](https://dmponline.dcc.ac.uk/)
  The requirements of the HRB’s DMP template can be found here [https://dmponline.dcc.ac.uk/template_export/181465590.pdf](https://dmponline.dcc.ac.uk/template_export/181465590.pdf)
- **HRB Open Research** is a 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). It is a fast way of sharing data and ensuring citations for underlying data sources. **All publications are indexed in PubMed.** HRB strongly encourage grant holders to use this platform to publish all research outputs including study protocols and registered reports.
- Outputs may include research articles, study protocols, case studies, research data notes, datasets, software code, clinical guidelines, nanopublications\(^8\), educational resources, reports, policy briefs and other relevant documents.

**2.7 Potential safety risks and ethical concerns**

Please address any potential risk and/or harm to patients or human subjects/participants in the research, if relevant. Please highlight any potential ethical concerns (including work involving animals) during this study and/or at follow-up stage. Describe any potential ethical concerns that may arise as a result of this research even if not part of this application and how you propose to deal with them. If the proposed research includes vulnerable groups; what additional considerations are there for these participants? The word limit is **100 words**.

**2.8 Compliance with Data Protection Regulations**

Please comment on how your study complies with The General Data Protection Regulation (EU) 2016/679, if relevant, especially where the study involves the transfer of data outside of the EU. The word limit is **200 words**.

**2.9 Objectives and deliverables Gantt Chart**

You must upload a **Gantt chart** which lists the objectives and deliverables against the estimated timeline.

\(^{16}\) All HRB Host Institutions must subscribe to the National Intellectual Property Protocol, ‘**Inspiring Partnership: the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland**’, prepared by Government/Knowledge Transfer Ireland to ensure transparent and consistent procedures for managing Intellectual Property from publicly funded research.

\(^{7}\) [https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-management-and-sharing-of-research-data/](https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-management-and-sharing-of-research-data/)

\(^{8}\) A nanopublication is the smallest unit of publishable information: an assertion about anything that can be uniquely identified and attributed to its author [http://nanopub.org/wordpress/](http://nanopub.org/wordpress/)
2.10 Project Description Figures
A file upload option is available to include an attachment to support your Project Description. A maximum of 5 figures, which can be a combination of images, graphs, tables, scales, instruments or surveys, may be uploaded as a single document on GEMS. They must not be embedded within the text of the Project Description. The maximum size is 2MB. Files should be doc, docx, or pdf.

3. Research Team Summary Table
Please fill the table to provide an overview to the review panel of the team members and their contribution to the project. The table should include each team member, such as lead applicant, co-applicants, collaborators and personnel. Additional information on the lead applicant and co-applicants are requested in section 4 and 5.

For each member please add the
- name,
- institution (affiliation),
- for each member of the team please list the role (e.g. Lead Applicant, Co-Applicant, Collaborator, Personnel type (e.g. Post-doctoral Researcher, Research Assistant, Nurse, etc) and the specific contribution to the project.

To expedite the process, Collaboration Agreement Forms will be requested during contracting and not as part of the application. Forms are available to download from GEMS (Supporting documentation section) and given the very tight timeline for contact negotiation it is recommended that Lead Applicants complete these documents as soon as possible.

Note: It is expected that most funded personnel will be redeployed from other research projects. Please note that this call is not suitable for a PhD candidate.

4. Lead Applicant’s Profile

4.1 Lead Applicant GEMS Profile Details
The Lead Applicant is required to fill in contact and basic information, including position and status (contract or permanent), in the ‘Manage my Details’ section of GEMS, which can be found on the left-hand side menu once you log in (if previously registered on GEMS this information will be pre-populated on the Lead Applicant’s Details page, however, applicants should ensure this information is up to date and correct).

Please note you do not need to complete or update your publications and your funding record under ‘manage my details’ as they will not feed through to this application. You will be asked to enter them manually in the section below.

4.1 ORCID
Lead applicants are encouraged to include an ORCID iD in their application. Please note this is not a mandatory field for submitting your application. For more information and to register please see http://orcid.org/

4.2 Personal declaration
Briefly describe why you are well-suited for your role as Lead Applicant in this project. You may describe any additional experience or expertise that will provide evidence of their ability to successfully lead and contribute to the proposed project.
The word limit is **100 words**.

4.3 Most relevant funding track record
Please reference **up to three independently peer-reviewed research** funding awards (including personal awards and awards received from the HRB or from the IRC) which are most relevant to this application and, please specify your role on each: Lead Applicant, Co-Lead Applicant; Co-Applicant (Partner) or Collaborator.

4.4 Research outputs
Please reference **up to three research outputs most relevant** to this funding application.

4.5 Total number of peer-reviewed publications
Please provide the total number of peer reviewed publications which you have authored and/or co-authored.

5. Co-Applicant’s Profiles
The Lead Applicant can add **up to 5 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 LA 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 LA to participate on the application as a co-applicant. **Registered Co-applicants** can decide whether to accept or reject their participation and **must consent to the application being submitted jointly in their name**. If a co-applicant rejects participation on an application the LA is informed and may revise the application accordingly. Co-applicants who accept participation in an application will be able to edit the application. The system will flag if another user is working on the application form at the same time via a pop-up warning. 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.

**Please note co-applicants do not need to complete or update the publications or funding record under ‘manage my details’ as they will not feed through to this application. They will be asked to enter them manually in the section below.**

Further details are requested about the Co-Applicant including their position and status (contract or permanent).

5.1 Personal declaration
Briefly describe why you are well-suited for your role in this project. You may describe any additional experience or expertise that will provide evidence of their ability to successfully contribute to the proposed project.
The word limit is **100 words**.

5.2 Most relevant research outputs
Please reference **up to three research outputs most relevant** to this funding application. If not applicable, please add N/A.
5.3 Total number of peer-reviewed publications
Please provide the total number of peer reviewed publications which you have authored and/or co-authored. If not applicable, please add N/A.

5.4 Collaboration

To expedite the process, **Collaboration Agreement Forms** will be requested during contracting and not as part of the application. Forms are available to download from GEMS (Supporting documentation section) and given the very tight timeline for contact negotiation it is recommended that Lead Applicants complete these documents as soon as possible.

6. Infrastructure & Support

**Host Institution, Infrastructure and Support**
Describe the infrastructure, facilities, specialist expertise and other support available at the Host Institution and/or at other sites where the research will be conducted. Please include details of critical supports in areas such as statistics, research methods, biobanking expertise where this is being provided above and beyond the activities/expertise of members of the research team. The word limit is **100 words**.

To expedite the process, **Infrastructure Support Forms** will be requested during contracting and not as part of the application. Forms are available to download from GEMS (Supporting documentation section) and given the very tight timeline for contact negotiation it is recommended that Lead Applicants complete these documents as soon as possible.

7. Project Budget

Please provide a summary and justification of the costs and duration associated with the project. **The total value of an award is typically €200,000 inclusive of overhead contribution.** In exceptional circumstances and where well justified this may be higher. **There is no set limit per annum** therefore the proposed budget per annum should reflect anticipated annual costs.

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

A **breakdown and justification of costings** 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 and IRC will not provide additional funding in the case of either under-estimates or over expenditure.**

Funds will be provided for the following:

<table>
<thead>
<tr>
<th>1. Personnel costs</th>
<th>Must be listed for each salaried personnel under each of the following subheadings (a-e):</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Salary</td>
<td>Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with host institution. Applicants are advised that public sector pay increases for the period until end of 2020 have been agreed. Please find new pay scales at <a href="https://www.iua.ie/research-innovation/researcher-salary-scales/">https://www.iua.ie/research-innovation/researcher-salary-scales/</a> If your application stretches beyond 2020; please apply a salary contingency of 2.5% p.a.</td>
</tr>
</tbody>
</table>
Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure.

**Applicants should include annual pay increments for staff and related costs (pension contribution, employer’s PRSI contribution, and overhead contribution) in the budget.**

**Note:** HRB and IRC do not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. HRB and IRC do not provide salary or buy out time for collaborators.

<table>
<thead>
<tr>
<th>b) Employer’s PRSI</th>
<th>Employer’s PRSI contribution is calculated at 11.05% of gross salary.</th>
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</thead>
<tbody>
<tr>
<td>c) Employer Pension Contribution</td>
<td>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 funders will not be liable for costs.</td>
</tr>
</tbody>
</table>

| 2. Running Costs | For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs etc. Maintenance costs of animals are allowed for pre-clinical animal models only. Access to necessary special facilities or services which are not available in the host academic or clinical institutions e.g. consultancy fees, methodological support, biobanking, Clinical Research Facility support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying ‘Infrastructure Agreement Form’ upload. |

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17 The maximum HRB allowable per diem rates for the maintenance of the most common strains of small animals are: mice (€0.50), other laboratory rodents (€1) and rabbits (€2). All per diem rates are inclusive of VAT at 21.5%. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis.
Costs associated with involving members of the **public or patients** in your research e.g. consultation workshops, costs of participation in advisory groups, travel expenses etc. should be charged to running costs.

The following costs are ineligible and will not be funded: training courses/workshops for funded research personnel, inflationary increases, cost of electronic journals.

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

<table>
<thead>
<tr>
<th>3. FAIR Data Management Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs related to data management, FAIRification, storage and archiving of research data in line with best practice of data management and stewardship and the FAIR principles <strong>incurred during the lifetime of the project</strong> should be included. Please consult Appendix 3 of this document for examples of eligible costs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €10,000. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e. overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified. All costs must be inclusive of VAT, where applicable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Dissemination Costs (including data sharing)</th>
</tr>
</thead>
<tbody>
<tr>
<td>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. <strong>Data sharing costs can be included here.</strong> Please refer to the HRB policy on Open Access to Published Research(^1^8). Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary.) Typically, the average HRB contribution towards publication costs is €1750/per article.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Overhead Contribution</th>
</tr>
</thead>
</table>
| 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 Costs if **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. |

\(^1^8\) [http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/](http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/)
8. Ethical approval and approvals for use of animals

Ethical approval is required for all research that involves human participants, human material (including tissue) or animals (pre-clinical models only). Applicants are responsible for ensuring that all necessary approvals are in place prior to the start of the research. Applicants should allow sufficient time to obtain ethical and/or competent authority approval and/or animal licenses as a copy of such approvals must be submitted to the HRB before the initiation of the award. It is suggested that these are sought in parallel to the submission of the application.

Submission of applications

The deadline for submission of complete applications is 7 April at 13.00.

1. After successful validation the Lead Applicant may submit the application. It will then be routed to the designated signatory at the Host Institution for their approval.
2. If a signatory rejects the application the Lead Applicant will be notified, along with any feedback the signatory has supplied.
3. The application can then be re-submitted; it will be returned to the signatory and will continue through the approval process as before.
4. On completion of the final approval by the Host Institution signatory, a grant application number is assigned to the application.
5. The application automatically gets submitted to the HRB through GEMS for consideration for funding.

Supporting documentation

List of supporting documentation to be provided before the contract is signed, if successful. The forms can be downloaded through GEMS and all the documents can be sent by email via GEMS prior to signing the contract.

These documents can be uploaded here and then submitted by email through GEMS.

- Signed Collaboration Agreement Form for each collaborator listed in the application;
- Signed Infrastructure Agreement Form, if applicable;
- **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 COVID-19 Rapid Response award as a contract researcher; (ii) has an independent office and research space/facilities for which he/she is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise post-graduate students and post-doctorate researchers; Electronic signatures are acceptable for these letters.
- Copy of Research Ethics Committee Approval (if applicable);
- Copy of Animal Licence (if applicable).

**Note**: Because of the very tight timeline for contract negotiation (5 working days), Lead Applicants should make sure these documents are in place immediately after the submission of the application and prior to hearing of the outcome of the review process. The HRB and IRC reserve the right to reject any application that does not meet the terms of this call.
Appendix 2: Resources/Useful Links

SFI, in partnership with Enterprise Ireland and IDA Ireland, is currently working to set up a COVID-19 related online information resource. Please check their website for information.

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

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

The Campbell Collaboration UK & Ireland: hub at Queens University Belfast
https://www.qub.ac.uk/research-centres/CampbellUKIreland/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies
http://www.equator-network.org/resource-centre/library-of-health-research-reporting/

CLINICAL RESEARCH INFRASTRUCTURES/SUPPORTS

Health Research Board Clinical Research Facility, Cork
http://www.ucc.ie/en/crfc/

Health Research Board Clinical Research Facility, Galway
http://www.nuigalway.ie/hrb_crfg/

Wellcome Trust-Health Research Board Clinical Research Facility, St James’s Hospital
http://www.sjhcrf.ie/

Clinical Research Centre, Royal College of Surgeons in Ireland
http://www.rcsicrc.ie/

Clinical Research Facility, University College Dublin
http://www.ucd.ie/medicine/ourresearch/researchenvironment/ucdclinicalresearchcentre/

Centre for Advanced Medical Imaging, St James’ Hospital Dublin
http://www.3tcentre.com/

Centre for Support and training Analysis and Research (CSTAR)
http://www.cstar.ie

Health Research Institute Clinical Research Support Unit Limerick
https://www.ul.ie/hri/clinical-research-support-unit

BIOBANKING
Council of Europe Recommendation of the Committee of Ministers to member States on research on biological materials of human origin (2016)
https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

OECD Guidelines on Human Biobanks and Genetic Research Databases
http://www.oecd.org/sti/biotech/guidelinesforhumanbiobanksandgeneticresearchdatabaseshbgrds.htm

ISBER Best Practices for Repositories
http://www.isber.org/?page=BPR

Molecular Medicine Ireland Biobanking Guidelines
http://www.molecularmedicineireland.ie/resources/biobanking-guidelines/

NCI Best Practices for Biospecimen Resources (2016 version)
http://biospecimens.cancer.gov/practices/

RESEARCH PRIORITIES & PUBLIC INVOLVEMENT IN RESEARCH

INVOLVE UK website for resources on Public and Patient Involvement in research
http://www.invo.org.uk

Patient-Centred Outcomes Research Institute (PCORI)
http://www.pcori.org

Public Involvement Impact Assessment Framework (Assess the impacts of involving members of the public in their research in diverse fields from health care to local history.)
http://piiaf.org.uk/

European Patient Forum Value + Handbook (For Project Co-ordinators, Leaders and Promoters On Meaningful Patient Involvement)

The James Lind Alliance Priority Setting Partnerships
http://www.lindalliance.org/Patient_Clinician_Partnerships.asp

USE OF ANIMALS IN RESEARCH

Experimental Design Assistant (EDA) (online tool for design of animal experiments)
https://www.nc3rs.org.uk/experimental-design-assistant-eda

ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines
https://www.nc3rs.org.uk/arrive-guidelines

SYRCLE (Systematic review of animal studies, register 2014-2017)
https://www.nc3rs.org.uk/arrive-guidelines

PROSPERO (Register for systematic reviews including animal studies 2018-)
https://www.nc3rs.org.uk/arrive-guidelines

GENDER ISSUES IN RESEARCH

Examples of case studies in Health & Medicine where gender/sex in research matters
http://genderedinnovations.stanford.edu/case-studies-medicine.html

Gender Toolkit in EU-funded research for examples and guidance

RESEARCH DATA MANAGEMENT PLANS

HRB Policy on Management and Sharing of Research Data
https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-management-and-sharing-of-research-data/

HRB Data Management Plan template
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

Data Stewardship Wizard created by ELIXIR CZ and NL
https://dmp.fairdata.solutions/

INFORMATION ON PERSISTENT IDENTIFIERS

DOI: List of current DOI registration agencies provided by the International DOI Foundation
http://www.doi.org/registration_agencies.html

Handle: Assigning, managing and resolving persistent identifiers for digital objects and other Internet resources provided by the Corporation for National Research Initiatives (CNRI)
http://www.handle.net/

PURL: Persistent Identifiers developed by the Online Computer Library Center (OCLC). Since 2016 hosted by the Internet Archive
https://archive.org/services/purl/

URN: List of all registered namespaces provided by the Internet Assigned Numbers Authority (IANA)
https://www.iana.org/assignments/urn-namespaces/urn-namespaces.xml

DATA REPOSITORIES

Registry of Research Data Repositories
http://www.re3data.org/

Data centers accredited by the German Data forum according to uniform and transparent standards (Germany)
https://www.ratswd.de/forschungsdaten/fdz

Zenodo Data Repository (OpenAIR)
https://zenodo.org/

**FAIR/OTHER USEFUL LINKS**

Main FAIR Principles
https://www.go-fair.org/fair-principles/

UK Concordat on Open Research Data (July 2016)
http://www.rcuk.ac.uk/documents/documents/concordatopenresearchdata-pdf/

Tool that helps to select and apply a license to a resource, provided by Creative Commons
https://creativecommons.org/choose/
Appendix 3: Data Management Costs

FAIR Data Management Costs (applicable to Lead Applicants from institutions participating to the HRB Pilot): 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:

<table>
<thead>
<tr>
<th>People</th>
<th>Staff time per hour for data collection, data anonymisation, staff time per hour for data management/stewardship support, training, etc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and computation</td>
<td>cloud storage, domain hosting charge</td>
</tr>
<tr>
<td>Data access</td>
<td>secondary data access, costs for preparing data for sharing (eg anonymisation)</td>
</tr>
<tr>
<td>Deposition and reuse</td>
<td>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</td>
</tr>
<tr>
<td>Others</td>
<td>Please further explain</td>
</tr>
<tr>
<td>Notes</td>
<td>The HRB is currently not covering the cost of long-term preservation of data</td>
</tr>
</tbody>
</table>

Please note that 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.