Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) Joint Transnational Call (2023)

"Development of innovative strategies, tools, technologies, and methods for diagnostics and surveillance of antimicrobial resistance"

Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	16 January 2023
Application Closing Date	7 March 2023 @13:00

Applications must be completed and submitted through the electronic submission system, and this system will close automatically at the stated deadline and timeline listed above.

This document provides additional guidance to researchers based in Ireland and seeking HRB funding as part of a transnational consortium. A summary of the call is presented herein along with eligibility criteria for Irish applicants requesting HRB funding.

This document must be read in conjunction with the call documents provided on the main JPI AMR call webpage, and the HRB FAQ for this call on the HRB call website.

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1 Introduction

The Health Research Board (HRB) Strategy (2021-2025)[1] sets out a lead role of the HRB to invest in research that delivers value for health, the health system, society, and the economy, as well as to foster and enhance European and international coordination, collaboration and engagement. In the field of antimicrobial resistance (AMR), the HRB works closely with European partners within the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) to support transnational research and network calls seeking new knowledge and supporting solutions to decrease the burden of AMR with a One Health approach.

AMR affects humans, animals and plants without geographic borders or species barriers. A holistic and multi-sectoral approach – referred to as One Health – is required to addressing the rising threat of AMR. Resistant pathogens and antimicrobials can be found in humans, animals, plants, food and the environment, and they may spread from one to another.

This call for research projects, developed under the ERA-Net JPIAMR-ACTION, is the 16th transnational call of the JPIAMR. The primary aim of the call is to combine the resources, infrastructures, and strengths of multiple countries in order to facilitate research projects supporting the development or improvement of existing strategies, tools, technologies, and methods to support the prudent and rational use of antimicrobials. This can be achieved by focusing on diagnosis of infections caused by resistant microorganisms, on detection of resistant microorganisms, and/or collection, analysis and use of AMR and antimicrobial use (AMU) data.

2 Aim and Objectives

To take action against the growing global threat of increasing resistance in pathogenic organisms, and the spread of AMR, this call aims to fund research projects that are developing novel or improving existing strategies, tools, technologies and methods for (1) diagnosis *and/or* (2) One Health AMR surveillance.

Diagnostics should aid "prudent use" and stewardship of antimicrobials e.g. through supporting pathogen and/or resistance pattern identification within clinical and community settings, or the use of appropriate antimicrobials in agricultural and environmental settings.

Surveillance should guide the understanding of the risk and direction of AMR spread and assist the development of interventions to limit the spread of AMR within and between humans, animals, plants and the environment.

It is expected that, through international collaborations combining complementary and synergistic research strengths, this JPIAMR call will result in the development of measures to limit the development and spread of AMR and address the urgent need to curb the burden associated with AMR. The results of the funded projects should contribute to improved understanding, monitoring, detection and mitigation of infection and AMR, or optimisation of AMU where efforts to curb AMR will have a global impact on human, animal and plant health and food safety and security.

[1] https://www.hrb.ie/strategy-2025/

3 Scope of Call

In the scope of this call, antimicrobials include antibiotics, antifungals and disinfectants (biocides).

Participation of end-users of the project outcomes, such as parties implementing antimicrobial stewardship activities, is encouraged.

3.1 Topics of the call

Projects should aim to address unmet needs in the AMR diagnostics and surveillance sectors beyond the current state of the art.

It is a requirement for applicants requesting HRB funding to include Human Health as the primary One Health Setting for their research activities.[2]

Applicants must focus on one of the below topics:

Topic 1:

To develop novel or improve existing diagnostics, including point of care diagnostics, that can rule out antimicrobial use or help identify the most effective antimicrobial treatment. Within this topic projects may:

- Develop new or improve/repurpose existing strategies, technologies, and methods for the rapid, accurate and affordable detection of bacterial or fungal infection and/ or resistance patterns and elements.
- Study ways to facilitate and implement the uptake and use of existing diagnostics in varied economic settings.[3]
- Optimise the use of tools, technologies, and methods for diagnostic data capture and usage, for example in conjunction with surveillance strategies.

Topic 2:

To develop novel or improve existing strategies, technologies, methods, or data use strategies to support One Health (OH) AMR surveillance. Within this topic projects may:

- Develop new or improve existing strategies, technologies, and methods for the detection, analysis, monitoring and use of AMR and AMU data. This can include the analysis of existing data or the application of existing surveillance strategies, technologies, and methods to additional OH settings.
- Explore the standardisation, FAIRification and linkage of methodologies, datasets and relevant indicators to perform globally comparative, integrated and triangulated surveillance of

[2] Where the primary focus of the project is animal/environment setting, Irish partners are advised to refer to the Department of Agriculture, Food and the Marine (DAFM). Irish Partner(s) planning an application covering animal/environment and human health One Health Settings are advised to consult with both Irish Funders (HRB and DAFM) to discuss eligibility requirements for funding prior to applying.

[3] Please check national requirements to ensure your national agency has the possiblity to fund social sciences and/or LMIC partners. Applicants based in Ireland shold refer to eligibility requirements in this document.

AMR/AMU in humans, animals (including companion animals, livestock and wildlife), plants, food, and the environment. Applicants are encouraged to consider:

- future development of a diagnostic or surveillance tool following the conclusion of the project,
- the data that needs to be obtained at an early stage to support downstream diagnostic regulatory consideration and market authorisation (consider new EU IVDR as relevant),
- the inclusion of appropriate partners (commercial or non-commercial) in the project to support downstream development,
- appropriateness of the proposed platform technology for the specific need,
- test costs and cost savings and how these align with the intended use case,
- the current competitive landscape and how it aligns with the articulated need.

3.2 One Health (OH) settings

The call covers the following OH settings:

- Human Health, and/or
- Animal Health (including wildlife, livestock, aquatic organisms, and companion animals), and/or
- Plants (including trees and crops), and/or
- Food, and/or
- Environment (including natural and built environment).

In the framework of this call, proposals addressing diagnostics (Topic 1) may focus within any individual OH setting. Surveillance-focused proposals (Topic 2) should focus within two or more OH settings. In case of proposals focusing on existing surveillance strategies, the proposal should extend to at least one additional OH setting.

3.3 Excluded approaches and topics

In the framework of this call all types of studies or experimental approaches are admissible but the eligibility of the proposed experimental approach may depend on your national funding organisation. Please see below for excluded activities for applicants for HRB applicants. Partners should confirm their eligibility according to the National Rules and Requirements of their relevant funding body (Annex B of the core call text).

The following sub-topics are **out of the scope** of the call:

- antiviral and antiparasitic agents,
- proposals solely aiming to extend existing surveillance networks (e.g. GLASS, national surveillance programmes).

In addition to the exclusions above, partners are not eligible for HRB funding for:

- Proposals not focusing primarily on Human Health. For those proposals addressing more than one OH setting, Human Health must be the primary focus of the Irish partner (see footnote 2).

- Proposals seeking to evaluate a pilot or feasibility study.[4]
- Proposals seeking to evaluate a definitive intervention.[5]
- Proposals involving basic biomedical research
- Research intended to create human embryos solely for the purposes of research or for the purposes of stem cell procurement, including by means of somatic cell nuclear transfer.

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

4 Funding Available, Duration and Start Date

The HRB plans to commit in the region of up to **€370,000** (inclusive of overheads) to the JPIAMR JTC2023 awards. Additional funding of up to €130,000 will be made available for coordination activities (excludes equipment and consumables), bringing the total maximum funding to **€500,000 for applicants who take on the role of coordinator**. Quality permitting a minimum of one award will be funded. Awards will have a duration of 36 months.

The award will offer research related costs for:

a) Personnel
   i. Salary-related costs in line with the IUA most recent scale for funded personnel
   ii. Stipends and fees (EU rate only)
   iii. Early Career Researchers salary related costs for a maximum of 0.5 FTE protected time for research funded by HRB for up to three years

b) Small equipment costs (not expected to exceed €10k)

c) Direct running costs (including travel, mobility costs and patient-related costs)

d) FAIR data management costs: Data stewardship costs (e.g. service/fees from data steward, access to secondary data, costs of making data FAIR, etc). Please refer to Appendix I for additional guidance on FAIR data management costings.

[4] **Feasibility studies:** For the purposes of this scheme, we adopt the concept of feasibility as described by Eldridge et al (2016). Eldridge describes 'feasibility' as an overarching concept, within which we distinguish between three distinct types of studies (1) randomised pilot studies (2) non-randomised pilot studies and (3) feasibility studies that are not pilot studies. This call is open to all types of stand-alone feasibility studies conducted in preparation for a future definitive trial of an intervention.

[5] **Definitive interventions: Intervention studies** of any appropriate design, including randomised controlled trials and non-randomised trials, are designed to assess the efficacy, effectiveness, cost and broad impact of a therapy or intervention. Interventions can be on individual human participants (patients or healthy volunteers), or alternatively could involve an intervention on an element of the health system, e.g. testing an intervention on healthcare setting, healthcare pathway, with the aim being to improve how healthcare is delivered. **Definitive interventions** should have potential for immediate use for decision makers in everyday clinical practice or policy, must have supporting feasibility information, and must have a basis in evidence that has been synthesised systematically.

e) Dissemination and knowledge exchange activities (including dissemination-related travel)

f) Overheads contribution

Please refer to Appendix I below for further guidance on FAIR data management costs.

Funding available is inclusive of overheads and pension contributions.

Note: The JPIAMR JTC2023 award will not fund the salary and related costs of tenured academic staff within research institutions (including buy-out from teaching time etc.). This does not apply to Early Career Researchers, as outlined above.

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

Projects are expected to start in Q1 2024.

5 Eligibility Criteria

Please also refer to Section 3 for excluded approaches and topics.

Each partner is strongly advised to check carefully the national eligibility rules defined by its relevant funding organisation, as specified in the National and Regional Requirements (Annex B of the core call text).

Applicants based in the Republic of Ireland who are targeting Animal Health and/or the Environment should refer instead to the guidance of the Department of Agriculture, Food and the Marine (DAFM).

Applicants based in Northern Ireland are not eligible for HRB funding for this call and must apply via the appropriate UKRI funding body.

5.1 Consortium Composition

A partner search tool is available for this call. Eligibility rules for the consortia are:

- The consortium must include a minimum of three eligible partners asking for funding from three different eligible countries[6] (including at least two amongst EU Member States or Associated Countries[7]).
- The consortium can include a maximum of six project partners (including non-funded partners). The maximum number of partners can be increased to seven if the consortium includes one or more of the following:

[6] Australia, Belgium, Canada, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Lithuania, Moldova, Netherlands, Poland, South Africa, Spain, Sweden, Switzerland, United Kingdom.

[7] https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf Note: UK is an EU country for the purpose of this call.

- at least one partner from an under-represented country (Lithuania, Moldova, Poland, and Least Developed Countries[8])
- at least one partner where the Principal Investigator meets the definition of an Early Career Researcher. Applicants for HRB funding should refer to the eligibility requirements below for the HRB definition. Other partners should refer to the core call text and/or guidance of their relevant funder
- a company (companies are not eligible for HRB funding).

Companies are welcome to apply to this call either by requesting funding or by using other internal or external funding. **Companies based in Ireland cannot be funded by the HRB.**

Project partners not eligible for funding may be involved in projects if they bring their own funding. The budget of non-funded partners must be included in the proposal and shall not exceed 30% of the requested total transnational project budget. The number of funded partners in the consortium must exceed the number of non-funded partners.

A project partner not eligible to be funded cannot be the coordinator of a proposal.

5.1.1 Lead Applicants based in Ireland seeking HRB funding

The following will apply to partners seeking HRB funding – i.e., Lead Applicants.[9] The **Lead Applicant** will serve as the primary point of contact for the HRB during the review process and on the award, if successful. The Lead Applicant will be responsible for the scientific and technical direction of the Irish research programme. They have 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.

Early Career Researchers (ECRs) are encouraged to join consortia as full research partners. ECRs seeking HRB funding should refer instead to the eligibility criteria in section 5.1.2 below.

The Lead Applicant **must**:

Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland (the "Host Institution") as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable.

OR

Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

[8] Least Developed Countries (LDCs) are low-income countries confronting severe structural impediments to sustainable development, according to the DAC list of ODA recipients https://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/DAC-List-of-ODA-Recipients-for-reporting-2022-23-flows.pdf. LDCs in sub-Saharan Africa can be funded by Sida. For details please consult Annex B of the core call text.

[9] 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.

They **must** show evidence of achievement as an independent researcher in their chosen research field by:

a) Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs (e.g., published book chapters, reports to government, research data and datasets, research materials, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence on health policy and practice, outreach and/or knowledge exchange activities, media coverage or other relevant activities) 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.

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

Each applicant can submit only one application as coordinator but can be involved in multiple proposals as partner.

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

5.1.2 Early Career Researchers (ECRs) as Lead Applicants seeking HRB funding

Early career researchers (ECRs) eligible for this scheme are **postdoctoral researchers** from different disciplines who are engaged in health-related research activities typically in **academic or other research institutions.**

The early career researchers are those who have already consolidated their research knowledge, skills, methodologies and capabilities through a period of mentored postdoctoral research and who are currently progressing towards becoming independent researchers.

Early career researcher Lead Applicants must be able to demonstrate they have the skills, knowledge and supports necessary to direct the proposed research and to carry the research through to completion by showing:

- Appropriate evidence of expertise matching the nature and context of the project;
- A track record of contribution to scientific knowledge demonstrated by relevant research outputs that can prove the Lead Applicant is ready to transition to research independence;
- Some experience, capability and authority to supervise researchers (e.g. early stage researchers, research assistants, other health and care practitioners);
- A track record in independently peer-reviewed grant funding. This may include being Lead Applicant on personal awards and/or fellowships and/or being listed as co-applicant and/or collaborator on any other type of research grant.

Qualification:

The ECR Lead Applicant must have:

- a PhD or
- have been granted PhD equivalence by the HRB (are proven to have at least four years of active research experience post-primary degree).

Note: **PhD equivalence** must be granted by the HRB before the call submission date and will not be considered after application submission. Contact HRB in relation to this approval process. PhD equivalence can be granted only to individuals who are not undertaking a PhD at the time of submission. Individuals currently studying for a PhD are ineligible to apply to this funding call. This includes individuals who have research experience prior to starting their PhD.

Note: Active research experience will be considered when assessing eligibility by the HRB and competitiveness of the track record of the Lead Applicants by reviewers. Career breaks, flexible working arrangements, changes in discipline and sector (e.g. industry, health organisation/agency) will be taken into account when assessing the research experience and scientific contribution to knowledge.

Career stage

The ECR Lead Applicants must have at least four years and up to seven years active post PhD (or equivalent) research experience.

For the purposes of this call the official date of a PhD is defined as the year that the dissertation was successfully defended. ECRs who defended their thesis in 2018 or before are eligible to apply unless they have gaps (e.g. career breaks, flexible working arrangements) in their curriculum vitae.

Employment history

The scheme is open to individuals who have the support of a HRB approved Host Institution in the Republic of Ireland.

The ECR Lead Applicant:

- must hold a fixed term post-doctoral or other research based positions that covers the duration of the award **or**
- is an individual who will be recognised by the Host Institution upon receipt of the EJP RD award as a post-doctoral researcher as defined above

  AND

- is requesting a maximum of 0.5 FTE of their own salary related costs **or**
- is not requesting their own salary

6 Host Institution

A HRB Host Institution is a research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all

general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all HRB award schemes. The **Host Institution for the award** is normally that of the **Lead Applicant** but it may be another organisation/institution designated by the research team, where it is clearly justified. In order to be eligible to apply for funding, an Institution must be an approved HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for research performing organisations to be approved as HRB Host Institutions can be found on the HRB website[10].

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.** These must be emailed to eujointprogrammes@hrb.ie before the pre-proposal submission deadline so that HRB staff can confirm eligibility. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*Host Institution - insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB [scheme] award as a contract researcher; (ii) has an independent office and research space/facilities for which they is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

7 Application, Review Process and Assessment Criteria

7.1 Application

There will be a two-stage application procedure for joined applications. One joint proposal document (in English) shall be prepared by the partners and must be submitted by the Coordinator in electronic format no later than 13:00 GMT on 7 March 2023 via the electronic submission system. **No other means of submission will be accepted.**

For further details, please refer to the respective submission forms available through the JPIAMR website. If you need additional information, please contact the Joint Call Secretariat (JCS). Please refer also to HRB Grant Policies.

Lead Applicants seeking HRB funding will be required to provide additional information to the HRB at the time of submission of full proposals. This will include justification for their requested budget, and clarification on deliverables assigned to the partner seeking HRB funding. Templates requesting this information will be provided by the HRB.

7.2 Review Process

International experts will perform a remote written evaluation of the proposals. Following the remote evaluation, the international experts will meet, agree on a consensus evaluation of the proposals and

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

recommend the pre-proposals that could be invited to submit a full proposal (stage 1) or the full proposals that could be recommended for funding (stage 2).

The adequacy of the proposals submitted to the call will be assessed by the evaluation panel. Proposals not relevant to the call topics and objectives will not be invited to submit a full proposal, regardless of their scientific quality.

Proposals selected for funding will undergo an ethics review by an Ethics Panel.

7.3 Assessment Criteria

Proposals will be assessed on Excellence, Impact and Quality and efficiency of the proposed research and its implementation. Evaluation scores will be awarded for the three main criteria. Each criterion will be scored out of five. See the core call text for full details.

In order for an application to be considered fundable, the threshold score for individual criteria is set at three (of a maximum of five). The overall threshold for the score for all three criteria together is set at nine. The maximum score that can be reached from all three criteria together is 15 points.

8 Timeframe

Date	
16 January 2023	Call Opening
24 January 2023 @11:00	Information webinar
7 March 2023 @13:00	Call Closing – pre-proposals
23 May 2023	Invitation for full proposal
4 July 2023	Call Closing – full proposals
November 2023	Final funding decision
Jan 2024	Earliest start date for Irish partners

9 Contacts

For further information on the JPIAMR call for “Development of innovative strategies, tools, technologies, and methods for diagnostics and surveillance of antimicrobial resistance” contact:

For general information, please contact the Joint Call Secretariat (JCS):

National Science Centre Poland
Jolanta Palowska and Monika Pobiega
E-mail: JPI.AMR@ncn.gov.pl

For country-specific information for Irish Partners seeking HRB funding, please contact the HRB:

Dr Siobhán Hackett
Email: eujointprogrammes@hrb.ie

Appendix I: HRB Funding Policies and Procedures

Public, Patient and Carer Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public, patients and carers in the research that we fund[11]. Public and patient involvement in research means that the public and patients are involved in planning and doing research from start to finish and help tell the public about the results of research. PPI, as defined here, is distinct from and additional to activities which raise awareness, share knowledge, and create a dialogue with the public, and it is also distinct from recruitment of patients/members of the public/carers as participants in research.

PPI represents an active partnership between members of the public, patients and carers and researchers in the research process. This can include, for example, involvement in the selection of research topics, assisting in the design, advising throughout or at specific decision points of the research project or in carrying out the research.

PPI contributors should be actively involved and part of decision making. Involving members of the public in research can improve quality and relevance of research. It can:

- Provide a different perspective - even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition.
- Help to ensure that the research uses outcomes that are important to the public.
- Identify a wider set of research topics than if health or social care professionals had worked alone.
- Make the language and content of information such as questionnaires and information leaflets clear and accessible.
- Help to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants.
- Help you increase participation in your research by making it more acceptable to potential participants.

In addition to improving relevance and quality of research, it ensures that research is influenced by broader principles of citizenship, accountability, and transparency. PPI is an ethos as well as a practice. It should be context-specific and should aim to ensure that all voices are heard. Where members of the public, patients or carers are involved, they must be compensated for their time and contributions.

In the application, you are asked to describe any public involvement in your research throughout the various stages of identifying and prioritising the research question, the research design, conduct, analysis, and dissemination. We recognise that the nature and extent of active public involvement is

[11] https://www.hrb.ie/funding/funding-schemes/public-and-patient-involvement-in-research/

likely to vary depending on the context of each study or award. PPI contributors should be named as Co-applicants where justified by their level of involvement.

For guidance and support on PPI in your research please consult with the PPI Ignite Network Ireland or your Host Institution. The PPI Ignite Network Ireland has offices located in the following seven Host Institutions: DCU, NUIG, RCSI, TCD, UCC, UCD, UL.

FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support open research[12] and open publishing directly through the HRB Open Research platform[13]. The HRB is driving the making of research data **FAIR** (**F**indable, **A**ccessible, **I**nteroperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles[14] provide a guideline for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals. For researchers, the move to FAIR and open data, where applicable, means researchers should consider data management issues and find suitable data repositories at the research planning stage. Applicants will have to provide information about their plans for data management and data sharing at application stage.

In line with the HRB's policy on management and sharing of research data[15], all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three months after the award start date, and a final updated version of the DMP with the last annual report.

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

Applicants will have to provide an outline of their plans for data management and data sharing in the application inclusive of the costs associated to the plan (see table below (p. 19) for guidance on costs.

The timing for completion and submission of the DMPs must be also included among the objectives and deliverables of the programme.

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

[13] https://hrbopenresearch.org/

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

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

General Data Protection Regulation

Personal information provided by an applicant will be processed in accordance with article 6.1 (c) or 6.1 (e) of the General Data Protection Regulation (GDPR) (2016/679) and for the purposes of:

- processing and evaluating the pre- and full proposal where processing shall be lawful only if and to the extent that processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
- administering any subsequent funding award;
- managing the relationship between the applicant and the Funding Partner Organisations (FPO);
- analysing and evaluating the call;
- providing aggregate data to national and European surveys and analyses on the funded projects;
- complying with audits that may be initiated by the Funding Partner Organisations and the European Commission (or its agencies).

In addition, by submitting an application (pre- and full proposal) to the AMR diagnostics and surveillance 2023 Call, the applicants agree to share their personal data with Funding Partner Organizations based outside the European Economic Area (see table on p. 16) and with third parties such as evaluators (some of which may be based outside the European Economic Area) in relation to the above activities.

The following FPOs outside the European Economic Area will use their national data protection rules: Australia (NHMRC), Canada (CIHR), Israel (CSO-MOH), Moldova (ANCD), South Africa (SAMRC), Switzerland (SNSF), the United Kingdom (UKRI).

By the time of the call launch, the European Commission issued adequacy decisions for personal data protection laws in Israel, Switzerland and the United Kingdom.

Funding Partner Organizations and third parties may link the data that applicants provide in the application with national, bibliographic or external research funding data which is available through public subscription based databases (e.g. Scopus, Web of Science, etc.) or other national/open datasets.

Use of personal data by HRB

By participating in this call, you agree to the use of the information you provide (regarding all applicant team members) for HRB to consider your application, contact you about your application, and if you are successful, to manage your grant throughout its lifetime in accordance with HRB general T&C for research awards.

This will include contacting you with regard to monitoring of progress through written reporting and other means e.g., interim review. We will publish some basic information on successful awards including PI, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended, we will continue to keep your information on file (in accordance with HRB policies) to allow us to evaluate the outcomes, outputs and impacts of HRB investment in your research.

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

The Health Research Regulations

Following the implementation of GDPR, a regulation for health research known as the Health Research Regulations 2018 (S.I. 314) has been implemented, with further amendments made in 2019 (S.I. 188) and 2021 (S.I. 18)[16]. These regulations outline the mandatory suitable and specific measures for the processing of personal data for the purposes of health research. They further set out that explicit consent is a mandatory safeguard that must be obtained from individuals when using their personal data for health research. Where it is not feasible to obtain explicit consent, an application for a consent declaration can be made to the Health Research Consent Declaration Committee[17].

Research on Research

The HRB is developing its approach to research on research (RoR) with the aim of enhancing the evidence base for HRB research funding practices. We may also collaborate with researchers on request regarding specific RoR questions. Should your application become of interest to such a study, the HRB will seek your consent for the use of your information.

Privacy Policy and Retention Policy

To understand why we collect the information we collect and what we do with that information, please see our Privacy[18] and Retention Policies[19].

Additional guidance on Costs

Personnel costs	**Must be listed for each salaried personnel under each of the following subheadings (a-c):**
a) Salary	Gross Annual Salary (negotiated and agreed with host institution). Applicants should use the IUA Researcher Salary Scales. Applicants are advised that public sector pay increases to October 2023 (inclusive) have been agreed. Please apply a salary contingency of 3% per

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

[17] https://hrcdc.ie/

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

[19] https://www.hrb.ie/fileadmin/user_upload/HRB_Document_retention_policy..docx

	annum from 1st October 2024. Please note this contingency should be applied cumulatively on 1st October year on year. Applicants should include annual pay increments for staff and related costs (pension contribution, employer's PRSI contribution, and overhead contribution) in the budget. 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.[20]
Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, trial-specific training for personnel etc. Please consult with your Host Institution in relation to trial-related insurance costs. 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 as long as they are detailed in an accompanying 'Infrastructure Agreement Form'. Costs associated with compensating PPI contributors involved in your research e.g., consultation workshops, time spent reviewing material, costs of participation in advisory groups, travel expenses, payments for time (in line with your Host institutions policies), etc. should be charged to running costs. The following costs are ineligible and will not be funded: animal study costs, inflationary increases, cost of electronic journals.

[20] 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.

	Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
Equipment	Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €10,000. Personal/Stand-alone computers 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.
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[21]. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary). Publications: Typically, the average HRB contribution towards publication costs is €1,750/per article or HRB Open Research: rapid open peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee. (www.hrbopenresearch.org) free of charge. Conferences: We envisage that conference costs will be typically around €500/year for national conference and €1,500/year for international conference.
FAIR Data Management Costs	Costs related to data-related and data management activities in line with best practice of data management and stewardship and the FAIR principles incurred during the lifetime of the project. Please see table below for further guidance.
Overhead Contribution	In accordance with the HRB Policy on Overhead Usage[22], 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.

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

[22] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-usage-of-research-overheads/

Additional guidance on FAIR Data Management Costs

People	Staff time per hour for data collection, data anonymisation, etc
	Staff time per hour for data management/stewardship support, training, etc
Storage and computation	Cloud storage, domain hosting charge
Data access	Secondary data access, costs for preparing data for sharing (e.g. anonymisation)
Deposition and reuse	Costs for depositing research data and metadata in an open access data repository
	Defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please provide explanations.
Notes	*The HRB is currently not covering the cost of long-term preservation of data*
	This list is not exhaustive and aims to provide examples only of eligible costs

Appendix II: Resources/Useful Links

REPORTING

COMET (Core Outcome Measures in Effectiveness Trials) Initiative: development and application of agreed standardised sets of outcomes, known as 'core outcome sets'

http://www.comet-initiative.org/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies

https://www.equator-network.org/library/

Registry of Research Data Repositories

http://www.re3data.org/

Zenodo Data Repository (OpenAIR)

https://zenodo.org/about

https://zenodo.org/

EVIDENCE SYNTHESIS

Evidence Synthesis Ireland: aims to build evidence synthesis knowledge, awareness and capacity among the public, health care institutions and policymakers, clinicians, and researchers on the Island of Ireland.

https://evidencesynthesisireland.ie/

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

www.thecochranelibrary.com

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

https://www.campbellcollaboration.org/

The Campbell Collaboration UK & Ireland: hub at Queens University Belfast.

https://www.qub.ac.uk/research-centres/CampbellUKIreland/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies.

http://www.equator-network.org/resource-centre/library-of-health-research-reporting/

BIOBANKING

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

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

BBMRI-ERIC is a European research infrastructure for biobanking

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

OECD Guidelines on Human Biobanks and Genetic Research Databases

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

ISBER Best Practices for Repositories

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

Molecular Medicine Ireland Biobanking Guidelines

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

NCI Best Practices for Biospecimen Resources (2016 version)

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

PUBLIC, PATIENT AND CARER INVOLVEMENT IN RESEARCH & RESEARCH PRIORITIES

The National PPI Ignite Network https://ppinetwork.ie/

NIHR PPI resources

https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437

Patient-Centred Outcomes Research Institute (PCORI)

http://www.pcori.org

Public Involvement Impact Assessment Framework: Provides tools for successful involvement of members of the public in research projects and for assessment of impacts.

http://piiaf.org.uk/

NIHR Payment guidance for researchers and professionals

https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392

European Patient Forum Value + Handbook: For Project Co-ordinators, Leaders and Promoters on Meaningful Patient Involvement.

http://www.eu-patient.eu/globalassets/projects/valueplus/doc_epf_handbook.pdf

The James Lind Alliance Priority Setting Partnerships: Research priorities in disease areas set jointly by patients, clinicians, and researchers.

http://www.jla.nihr.ac.uk/

Campus Engage: Supporting Irish HEIs to embed civic engagement in their work. Includes resources, how-to-guides, and case studies for engaged research.

http://www.campusengage.ie/what-we-do/publications/

UK Standards for Public Involvement: The six UK Standards for Public Involvement provide clear, concise statements of effective public involvement against which improvement can be assessed.

https://sites.google.com/nihr.ac.uk/pi-standards/home

USE OF ANIMALS IN RESEARCH

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

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

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

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

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

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

PROSPERO (Register for systematic reviews including animal studies 2018)

https://www.crd.york.ac.uk/PROSPERO/

GENDER AND/OR SEX ISSUES IN RESEARCH

Examples of case studies in Health & Medicine where gender/sex in research matters

http://genderedinnovations.stanford.edu/case-studies-medicine.html

Gender Toolkit in EU-funded research for examples and guidance

http://www.yellowwindow.be/genderinresearch/downloads/YW2009_GenderToolKit_Module1.pdf

Sex/Gender Influences in Health and Disease

https://orwh.od.nih.gov/sex-gender/sexgender-influences-health-and-disease

Methods and Techniques for Integrating Sex into Research

https://orwh.od.nih.gov/sex-gender/methods-techniques-integrating-sex-research

NIH Policy on Sex as a Biological Variable

https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable

DATA MANAGEMENT AND SHARNG AND FAIR PRINCIPLES

Digital Curation Centre: How to develop a data management and sharing plan and examples DMPs.

http://www.dcc.ac.uk/resources/data-management-plans/guidance-examples

FAIR data principles FORCE 11

https://www.force11.org/fairprinciples

UK Concordat on Open Research Data (July 2016)

https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

FAIR at the Dutch centre for Life sciences

https://www.dtls.nl/fair-data/

Registry of Research Data Repositories

http://www.re3data.org/

RESEARCH DATA MANAGEMENT PLANS

Data Stewardship Wizard created by ELIXIR CZ and NL

https://dmp.fairdata.solutions/

DMPonline of the Digital Curation Centre (DCC), UK

https://dmponline.dcc.ac.uk/

DMPTool of University of California Curation Center of the California Digital Library (CDL), USA

https://dmptool.org/

RDMO Research Data Management Organiser of the German Research Foundation, Germany

https://rdmorganiser.github.io/en/

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

KNOWLEDGE TRANSLATION RESOURCES

Health Service Executive Research & Development Main Page

https://hseresearch.ie/research-dissemination-and-translation/

Health Service Executive Research & Development: Knowledge Translation, Dissemination, and Impact A Practical Guide for Researchers

https://hseresearch.ie/wp-content/uploads/2021/04/Tools-and-templates-.pdf

Integrated Knowledge Translation (iKT) NUI Galway

https://www.nuigalway.ie/hbcrg/ikt/

The Canadian Institutes of Health Research: Guide to Knowledge Translation Planning

https://cihr-irsc.gc.ca/e/45321.html

Training Institute for Dissemination and Implementation Research in Health: Open Access Course

https://cancercontrol.cancer.gov/is/training-education/TIDIRC-open-access

IMPLEMENTATION SCIENCE RESOURCES

Centre for Effective Services

https://www.effectiveservices.org/resources/implementation

UCC Implementation Science Training Institute

https://www.ucc.ie/en/cpd/options/medhealth/cpd1778uccimplementationsciencetraininginstitute/

European Implementation Collaborative

https://implementation.eu/resources/

CO-CREATION RESOURCES

ACCOMPLISSH Guide to impact planning

https://www.accomplissh.eu/publications-and-deliverables

Working together to co-create knowledge: A unique co-creation tool – Carnegie UK Trust

https://www.carnegieuktrust.org.uk/publications/working-together-to-co-create-knowledge-a-unique-co-creation-tool/

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/