ERA-NET Neuron Joint Transnational Call "Mechanisms Of Resilience And Vulnerability To Environmental Challenges in Mental Health" (2023)

Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	10th January 2023
Application Closing Date	7th March 2023 @ 13:00

Applications must be completed and submitted through the PT-Outline (ptoutline.eu) *and this system will close automatically at the stated deadline and timeline listed above.*

This document provides additional guidance to researchers based in Ireland applying to this call 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 ERA-NET Neuron Call Webpage 2023 „Resilience and Vulnerability in Mental Health“ - ERA-NET NEURON (neuron-eranet.eu) **and the call FAQ on the HRB call website.**

Table of Contents

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 mental, neurological, and sensory disorders, the HRB works closely with European partners within the ERA-NET NEURON network to coordinate and optimize research efforts and funding programmes.

Maintenance, improvement, and restoration of human health including mental well-being are of fundamental importance and a worldwide priority. Mental disorders in particular depression and anxiety are the leading cause of disability worldwide and the third leading cause of overall disease burden (in Disability-adjusted life years, DALYs). According to the OECD, one in every two people experience mental illness in their lifetime. These figures might steadily increase in the following years as a consequence of recent global and regional crises. These facts highlight the importance of improving our understanding of the pathophysiological and adaptative mechanisms with the potential to develop therapeutic and preventive approaches to preserve and improve mental health in Europe and worldwide.

Mental health may be affected by environmental, lifestyle, social, economic adverse factors which increase the risk of developing long-lasting mental health conditions. Nevertheless, environmental stress produces different reactions among individuals who experience it. In response to the same environmental stressor some individuals will activate dynamic and self-organized mechanisms enabling beneficial emotional and behavioural adaptations leading to the development of 'resilience'. In contrast, some others will be more 'vulnerable' and prone to developing mental health conditions.

The 'Network of European Funding for Neuroscience Research' (NEURON) has been established under the ERA-NET scheme of the European Commission (www.neuron-eranet.eu). Under ERA-NET NEURON, a joint transnational call (JTC 2023) in the field of **resilience and vulnerability for mental diseases** is now launched. The following funding organisations have agreed to fund the joint call for multinational research projects in this scientific area. The call will be conducted simultaneously by the respective national and regional funding organisations their respective and coordinated centrally by the Joint Call Secretariat.

2 Aim and Objectives

The aim of the call is to facilitate multinational, collaborative research projects that will address critical translational questions to improve our knowledge concerning neurobiological mechanisms involved in resilience or vulnerability to environmental challenges in mental health.

It is presently unknown how traumatic and/or stressful events and adverse environmental context become neurobiologically embedded, increasing the vulnerability to mental disorders. Present hypotheses pinpoint to genetic and epigenetic risk factors as well as endocrine, and immune reactions as possible mechanisms. Similarly, how biological, social, cultural, psychological, and ecological factors manifest in neurophysiological mechanisms for the development of individual

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

coping capabilities to enhance resilience towards adverse experiences is presently poorly understood.

3 Scope of Call

The present call aims to fund preclinical research up to proof-of-concept clinical studies[2] addressing neurobiological mechanistic understanding of vulnerability and resilience to mental disorders. Research areas may cover a broad range of aspects including among others genetic, epigenetic, anatomical, molecular, immunological, and endocrine mechanisms. Proposals aiming at developing predictive, preventative, diagnostic and/or therapeutic approaches with the potential to enhance resilience based on known or hypothesized neurobiological mechanisms are within the scope of this call, as are proposals to understand the neurobiological basis of therapeutic technologies promoting resilience.

3.1 Topic Lists

Research proposals should cover at least one of the following areas:

a) Fundamental research addressing mental health vulnerability and resilience including the pathogenesis, aetiology, progression, treatment, and prevention of mental diseases initiated by exposure to adverse environmental challenges. This may include the use of knowledge on neurobiological mechanisms for the development of innovative technologies with the potential to promote mental health, reduce the incidence of mental disorders and improve clinical outcomes.

b) Clinical research addressing mental health vulnerability and resilience aiming to develop novel strategies for prevention, diagnosis, patient stratification, therapy and/or rehabilitation for mental diseases initiated by exposure to adverse environmental challenges. This may include research proposals aiming at the identification of neurobiological targets to enhance resilience. Applicants should demonstrate that they have the expertise and skills required to conduct the study including already established external collaborations.

Additional elements that need to be considered in the application:

- The translational value for human disease must be addressed explicitly in the proposals. If used, the choice of the animal model must be justified in the context of human pathology. The development of new animal or cell models is allowed if clearly justified and only if appropriate models are not available.
- Clinical studies are eligible up to the point of proof of concept.
- Multimodal and multicentre clinical studies are highly encouraged.
- The proposals should consider the cultural, societal background and general individual diversity if relevant.

[2] Eligibility and funding requirements for clinical trials vary between the partner countries. Clarification may be obtained from the individual funding organisations

- ERANET NEURON will not fund the establishment of large cohorts, but the use of existing cohorts, biobanks/brain banks and exploitation of existing data sets is encouraged.
- Appropriate access to relevant, well-characterized patient populations or suitable biomaterial collections must be demonstrated.
- The proposal should describe plans to make data available for the research and clinical communities.
- If relevant, it is recommended that the appropriate European infrastructures are contacted early in the planning of the projects; the following are potentially of interest for the applicants to this call: EATRIS-ERIC (focused on translational medicine), BBMRI-ERIC (focused on biobanking), EBRAINS (focused on data and tools for brain-related research) and ELIXIR (focused on data sharing).
- The ERA-NET NEURON seeks to strengthen patient engagement in research. All applications should include a description of expected outcomes with potential relevance for patients. Applicants are expected to engage patients, their care givers or patient organisations as appropriate in the research. Meaningful patient engagement can occur at the level of research planning, conducting research or disseminating research results. Patient representatives will assess patient engagement aspects, the feasibility, and the relevance of the full proposals from a patient perspective.
- Applicants should demonstrate that they have the expertise and skills required to conduct the study including already established external collaborations.

Applicants should refer to HRB's Appendices below for further guidance and resources on the above.

3.2 Excluded approaches and topics

- Neurodegenerative disorders that are addressed by the EU Joint Programme – Neurodegenerative Disease Research (JPND)[3].
- Proposals focusing on existing pharmacological treatments with their current indications
- Proposals focusing solely on technological developments in disregard of neurobiological mechanisms

[3] Alzheimer's disease and other neurodegenerative dementias, Parkinson's disease (PD) and PD-related disorders, Prion disease, Motor neuron diseases, Huntington's disease, Spinocerebellar ataxia, Spinal muscular atrophy

In addition to the exclusions above, Irish Partner(s) are not eligible for HRB funding for:

- 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
- 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.

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 will provide funding for projects up to a maximum of **€370,000** (inclusive of overheads) to the ERA-NET Neuron 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 coordinators**. Quality permitting a minimum of one award will be funded. Awards will have a duration of 36 months.

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 0.5FTE protected time for research funded by HRB for up to three years

[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.

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

Direct running costs (including travel, or mobility costs)

FAIR data management costs: Data stewardship costs (e.g., service/fees from data steward, access to secondary data, costs of making data FAIR, etc.)

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

c) Overheads contribution

d) **Funding available is inclusive of overheads and pension contributions.**

e) **Note: The HRB's ERA-NET Neuron award will not fund the salary and related costs of tenured academic**
f) **staff within research institutions (including buy-out from teaching time etc.).**

The budget requested and the 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 application.

Projects are expected to start in Quarter 1 2024.

5 Eligibility Criteria

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

This call is not open for Host Institutions from Northern Ireland.

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 Consortium Composition

The use of the matchmaking tool is strongly encouraged to build multidisciplinary research projects: https://connect.eventtia.com/en/public/events/jtc2023matchmaking/registration/attendees.

1. Only transnational projects will be funded.
2. Each consortium submitting a proposal must involve three to five principal investigator (PI) partners (referred to as partners below) from at least three different participating countries (see list in section 10 of the core call guidance). In specific cases this can be increased to six partners, as follows:
    a) The inclusion of partners from participating countries usually underrepresented in projects (Hungary, Lithuania, Poland, Slovakia, Sweden and Türkiye).
3. The inclusion of Early Career Researchers[6] as full partners (see section 5.1) is highly encouraged and will be part of the evaluation criteria.

[6] **4-7 years of experience since completion of PhD** or medical specialization diploma **at the date of the launch of this call** and a scientific track record showing great promise. Allowed extensions 18 months maternity leave, duration of paternity

4. No more than two eligible partners from the same country can be present in each consortium; further national/regional limits may apply, see "Guidelines for Applicants". PAOs requesting funding do not count toward the total.
5. A single PI will represent each project partner.

5.1.1 Coordinator

Each consortium must nominate a coordinator who represents the consortium externally and is responsible for its internal management (e.g., the application procedure, coordination of consortium agreement drafting, Data Management Plan, reporting). The consortium coordinator must be eligible project partner from an ERA-NET Neuron JTC 2023 funding country/region. This workload should be considered in the estimation of the budget of the coordinator – the HRB will make available additional funds of up to €130,000 for Irish coordinators for this purpose.

5.1.2 Lead Applicants Based in Ireland

The following will apply to partners seeking HRB funding – i.e., Lead Applicants based in Ireland [7].

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 based in Ireland should refer to the eligibility criteria in section 5.1.3 rather than the below.

The Irish 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

leave, duration of long-term illness or national service, duration of clinical training with a maximum of 4 years). *Please check the funder specific regulations for the national/regional eligibility criteria that apply.*

[7] 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.

award, for which they will be fully responsible. The Irish Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

They **must** show evidence of achievement 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.

5.1.3 Early Career Researchers as Lead Applicants based in Ireland

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

5.1.4 Collaborators

In order to be considered as an eligible partner, a group must contribute substantially to at least one of the project's work packages. If the only role of a group is to provide patient access, data or samples for the study, they will not be considered as partners of the consortium, but can be included otherwise, via cooperation agreements or subcontracting.

Consortia may include collaborators that secure their own funding. Collaborators cannot be work package leaders, and their contribution to the consortium must be described (where relevant a CV can be included in the proposal).

If necessary to implement the action, consortia may also include sub-contractors, according to country/regional regulations. Sub-contractors may cover only a limited part of the action, and their contribution to the consortium must be described.

Collaborators and sub-contractors do not count toward the limit of 8 partners requesting research funding (nor is there a limitation of subcontractors per country, as long as their participation is justified and if subcontracting is possible according to national/regional funding rules).

5.1.5 Patient Advocacy Organisations and Patient Involvement

Consortia are strongly advised to include patient representatives and patient advocacy organisations (PAOs). **Please see Appendices below for HRB guidance.**

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 **Irish 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[8].

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

Host Institution Letters of Support should be emailed to eujointprogrammes@hrb.ie before the pre-proposal submission deadline. These are required to confirm eligibility.

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

7 Application, Review Process and Assessment Criteria

7.1 Application

There will be a 2-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. All fields must be completed using DIN-A4; font: Arial, 10pt; single-spaced, page limits. Pre-proposals that do not meet the formal criteria will be rejected from the call process without further review.

For further details, please refer to the respective submission forms available through the ERA-NET Neuron Resilience call 2023 If you need additional information, please contact the Joint Call Secretariat (JCS). Please refer also to HRB Grant Policies.

Irish Lead Applicants 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 from Ireland. A template requesting the information required from applicants from Ireland will be provided by the HRB.

7.2 Review Process

7.2.1 Pre-proposal

Eligibility Check

The JCS will check all pre-proposals to ensure that they meet the call's formal criteria. The JCS will forward the proposals to the CSC members who will perform a check for compliance to country/regional eligibility rules.

Peer-Review

Eligible pre-proposals will be reviewed using the evaluation criteria via a written (remote) peer review process. Preferably, each pre-proposal will be reviewed by at least three reviewers. Based on the scores in the written reviews a ranking list will be established. By mid-May 2023, the coordinators of the selected proposals will be invited by the Joint Call Secretariat to submit a full proposal before **29th June 2023 13:00.**

7.2.2 Full proposal

The international Peer Review Panel will evaluate the full proposals based on the above-mentioned evaluation criteria and establish a ranking list based on scientific assessment at the panel meeting. Additionally, expert patient reviewers will assess the patient relevant aspects of the full proposals and an Ethics board will give recommendations on the ethical aspects of the full proposals. A short list of proposals will be identified as recommended for funding based on the ranking list. The Call Steering Committee will determine the projects to be funded, considering the national budgets' availability.

7.2.3 Funding decision

Based on the ranking list established by the SEC and on available funding, the CSC will suggest the projects to be funded to the national/regional funding organisations. Final decisions will be made by the national/regional funding organisations and will be subject to budgetary considerations.

The JCS will notify all project coordinators of the final funding decision and disseminate the SEC consensus report.

7.3 Assessment Criteria

Evaluation scores will be awarded according to specific evaluation criteria that are in line with Horizon 2020 rules – excellence, impact and quality & efficiency of implementation – using a common evaluation form. Each criterion will be scored out of five, for a maximum overall score of 15 points. The threshold for an individual criterion is three, with an overall threshold of 12 points.

8 Timeframe

Date	
10 January 2023	Call Opening
07 March 2023 13:00	**Call Closing Pre-Proposal**
May 2023	Invitation to Full Proposal
29 June 2023	**Call Closing Full Proposal**
October 2023	Deadline for Rebuttals
November 2023	Funding Decision

9 Contacts

For further information on the ERA-NET Neuron contact:

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

German Aerospace Centre project Management Agency, DLR-PT
Dr Sophia Schach
E-mail: neuron-eranet@dlr.de

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

Ms Harriet Lovett
Email: eujointprogrammes@hrb.ie

Appendix I: HRB Funding Policies and Procedures

Access and support from research infrastructures

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), HRB-TNRN, Cancer Groups, National clinical trials office (NCTO), CTNs 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).

An Infrastructure Agreement form will be requested as part of the application addressing the nature/scope of the service or collaboration, the rationale behind the choice of facility/centre/network and any costs associated with the project (including those provided as in-kind contributions). Applications proposing research with patients which do not detail advice and/or support from a CRF/CRC/CTU will be asked to justify why they have not done so.

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[9]. 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.

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

- 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 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[10] and open publishing directly through the HRB Open Research platform[11]. 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[12] 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[13], 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.

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

[11] https://hrbopenresearch.org/

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

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

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.

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

General Data Protection Regulation

Applicants are informed that their personal data submitted in their application to the call are processed in accordance with article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679)[14], and for the purposes of

- processing and evaluating the application 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 funding organizations relationship with them;
- analysing and evaluating the call;
- providing aggregate data to national and European surveys and analyses on the funded projects; and

The Call Steering Committee may share applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).

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

[14] Last name, first name of the researchers, date of birth, professional contact information, degree(s), position (current and previous), fields of activity, place of work, organisation, address(es), curriculum vitae, ORCID number, name and reference of projects, pre-proposals, project proposals (scientific document, administrative and financial appendix).

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)[15]. 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[16].

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[17] and Retention Policies[18].

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

[16] https://hrcdc.ie/

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

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

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/