ERA4Health Joint Transnational Call "Increasing health equity through promoting healthy diets and physical activity (HealthEquity)" (2023)

Guidance Notes

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Key Dates & Times	
Application Open	13 January 2023
Application Closing Date	14 March 2023 @14:00

Applications must be completed and submitted through the ERA4Health 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 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 main ERA4Health call webpage, and the HRB FAQ for this call 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. The HRB works closely with European partners to address Europe's most pressing challenges. In 2022, the HRB joined a new initiative named ERA4Health, an EU partnership[2] whose vision is to foster a European Research Area for health. The EU-funded ERA4Health Partnership brings together 32 entities and 27 funding organisations from 21 countries, with the common goal of fostering high-impact translational research for addressing public health needs.

.Unhealthy diets and inadequate physical activity exacerbate the risk of poor physical and mental health. Socio-economically disadvantaged groups are particularly affected, leading to further health inequities between social groups. There is a need to understand, predict and ultimately change the circumstances determining citizens' lifestyle and health behaviours, permanently. Research has shown that many current intervention strategies targeting the individual do not result in sustained improvements in dietary and physical activity behaviours.

Accordingly, there is a clear need to take a broader perspective of the surrounding environment leading to these behaviours, i.e. not only with respect to the food and built environment for physical activity, but also the family, social, cultural, and local background, as well as digital influences. Following that, targeted innovative strategies leading to long-term behavioural changes need to be developed in order to reduce health inequities.

This call contributes to the aims and ambitions of the ERA4health Partnership by addressing European public health needs with the establishment of transnational, collaborative and multi-disciplinary research networks. It follows the ambition of ERA4health that the health and well-being of every citizen must guide policy development.

2 Aim and Objectives

The aim of this call is to develop novel strategies and targeted approaches to identify, understand, and modify determinants and mechanisms of diet-related behaviour and physical activity as well as sedentary behaviour, which have the potential to break through the cycles maintaining unhealthy behaviours and lifestyles and to reduce health inequities.

The expected results have the potential to improve the health and well-being of socio-economically disadvantaged groups through targeted approaches for a long-term behaviour change in the areas of healthy diet and physical activity. Different areas of public action will be targeted following the "Health in all policies" approach. The research results should be translated into policy

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

[2] Under Horizon Europe, the European Commission is introducing a more strategic, coherent and impact-driven approach to working with private and/or public sectors. 'European Partnerships' will be the new framework for programme level collaboration between the Union and public or private partners.

recommendations or actions, empowering governments and local communities and other policymakers to improve the food environment and built environment for physical activity.

Moreover, the coordination of the transnational research networks will also contribute to important research-related activities such as harmonisation of protocols, establishment and sharing of data and guidelines or/and sharing of research facilities and capacities.

3 Scope of Call

Proposals **must clearly demonstrate the potential health impact and/or policy impact** as well as **the added-value of transnational collaboration** i.e. through sharing of resources (models, registries, diagnosis, etc.), harmonisation of data, sharing of specific know-how and/or innovative technologies.

The individual project partners of the joint applications should be complementary and the proposed work should contain novel, innovative and ambitious ideas with a high implementation potential to be of benefit for citizens.

Research should be targeted at socio-economically disadvantaged groups and their setting, including the family, social, cultural, and local background, as well as digital influences. Applicants need to clearly define and justify their selection of target group(s). In addition, the strategy for reaching these target groups must be innovative and outlined in detail.

Proposals should comprise holistic and multi-disciplinary research, that must include several approaches tackling different aspects, such as:

- Mapping the current situation of the vulnerable groups with respect to food and built environment for physical activity;
- Developing and testing innovative interventions/ targeted strategies, that
  - may target the food environment and/or the built environment for physical activity and/or
  - may address illiteracy by increasing knowledge with respect to food, lifestyle and adequate use of digital media and/or
  - may be focussed on different settings, including but not limited to day-care, schools, workspace, retirement homes, neighbourhood, and/or
  - may use a life course approach.
- Evaluating existing interventions, e.g. to identify barriers in the implementation;
- Assessing the efficiency of policies and fiscal approaches (e.g. taxes and subsidies) that were implemented to enhance healthy diets and physical activity;
- Expanding the theoretical basis on the systemic barriers to change, e.g. political, economic and/or cultural barriers to increase the effect of interventions.

The research results should have a clear potential to be translated into policy recommendations or actions.

Beyond that, the following points should be taken into account:

- Involvement of citizens/stakeholders:

  - It is strongly recommended to involve stakeholders in the projects, e.g. political representatives (local/regional/national), citizens and/or citizen representatives, local communities, schools, municipalities, local/ national NGOs, consumer organisations.
  - Involvement of stakeholders should start as early in the process as suitable for the research, ideally already in the conception stage.
  - The type of stakeholders and level of involvement depends on the design, e.g. for new interventions it should be co-creation. Applicants should clearly explain their reasons behind (not) involving certain stakeholders.
  - Stakeholders can be directly involved in the project as funded partner (depending on the respective national regulations for funding of stakeholders; see Annex I of the core call text), collaborator, or as part of an advisory board. HRB cannot fund stakeholders as a funded partner but their costs may be covered under the project running costs (see section XX below).
  - Dissemination activities only are NOT sufficient in terms of co-creation/participation of stakeholders.
- Proposals should consider potential moderators of effects such as age, sex, gender, ethnic or other (socio-)demographic features/differences in the respective research approaches.
- Proposals should make use of existing cohorts, if applicable. Otherwise, it should be explained why existing cohorts are not used.
- The way policies (social domain) determine health should be in accordance with a HiAP (Health in All Policies) perspective.

Proposals should follow the principles of Responsible Research and Innovation (RRI). All consortia should demonstrate a commitment for investigating and addressing the social, ethical, political, environmental or cultural dimensions of the proposed research. For further information please refer to the "Guide for applicants".

Research supported by ERA4Health must respect fundamental ethical principles. Applicants have to describe any potential ethical aspects of the work to be carried out, and how the project will fulfil applicable requirements in institutional, national and European Union legislation (including the ethical standards and guidelines of Horizon Europe).

For Irish applicants planning to conduct a feasibility/interventional study, they are required to address all components of the **checklist for interventional studies** within Annex D of the core call text.

Irish Partner(s) are not eligible for HRB funding for:

- 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

Please note: Project partners will be funded by their relevant national/regional funding organisations. **Eligible costs and funding rules may vary** between the respective funding organisations (see Annex I of the core call text).

For applicants based in Ireland, the HRB plans to commit in the region of up to **€370,000** (inclusive of overheads) to the ERA4Health 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)
b) Small equipment costs (not expected to exceed €10k)
c) Direct running costs (including travel, mobility, patient-related costs and costs to support interventional studies)
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.
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 and costs for interventional studies.

Funding available is inclusive of overheads and pension contributions.

Note: The HRB ERA4Health award will not fund the salary and related costs of tenured academic 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 assess the level of funds and timeframe requested when reviewing the application.

Projects are expected to start by May 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.

Please note that **additional conditions might apply at national level** (see Annex I of the core call text).

5.1 Consortium Composition

Each project partner will be represented by one principal investigator. From the principal investigators each project consortium must nominate **a project coordinator** (NOT a collaborator). The project coordinator will represent the consortium externally and towards the JCS and Call Steering Committee (CSC, i.e. the funding organisations' representatives) and will be responsible during the entire process for its internal scientific management such as controlling, overseeing IPR issues, reporting, and contact with the JCS.

Only transnational projects will be funded. The European Commission's **partner search tool** can be used to identify potential partners.

The following conditions apply to the composition of consortia:

- A minimum of three eligible and a maximum of five eligible partners from at least three different countries participating in the call.[3]
- The maximum number of eligible partners can be increased up to six or seven if they include one or two partners, respectively, from the following participating, potentially underrepresented countries: Latvia; Lithuania; Slovakia; Türkiye.
- No more than two eligible partners from the same country participating in the call will be accepted within one consortium.
- A maximum of two collaborators per consortium (see section 5.1.2 for information on collaborators).

The number of participants and their research contribution should be appropriate for the aims of the transnational research project and be reasonably balanced in terms of international participation. Each transnational collaborative project should represent the critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from working together.

5.1.1 Lead Applicants based in Ireland

The following will apply to partners seeking HRB funding – i.e., Lead Applicants based in Ireland.[4] 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.

[3] Belgium, Denmark, France, Germany, Ireland, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, Spain, Taiwan, The Netherlands, Türkiye

[4] In view of the overwhelming evidence that both active and passive smoking of tobacco are injurious to health, the HRB is unwilling to fund applications from individuals applying for, holding, or employed under a research grant from the tobacco industry.

The Lead Applicant based in Ireland **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 based in Ireland 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.

Each Lead Applicant can submit only one application as coordinator or up to two proposals as partner.

Please note that if a partner is found to be non-eligible by one of the funding organisations at any step of the process, the entire proposal could be rejected without further review. The Joint Call Secretariat will contact the consortium in the event that this situation arises.

5.1.2 Collaborators

Collaborators are self-funded partners that do not request funds for this Joint Transnational Call from one of the participating funding organisations, ; i.e. partners from non-funding countries, or partners that are not fundable according to national/regional regulations of the participating funding organisations.

The following conditions apply for collaborators:

- Clear added value for the research project. This should be demonstrated in the application.

- Secure own funding for participation with clear evidence in the proposal that this is already in place.
- A letter of commitment of the collaborator(s) needs to be included as an annex to the proposal.

A collaborator cannot be work package leader.

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** based in Ireland 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[5].

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 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 one-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 14:00 GMT on 14 March 2022 via the electronic submission system. **No other means of submission will be accepted.**

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

For further details, please refer to the respective submission forms available through the ERA4Health website. If you need additional information, please contact the Joint Call Secretariat (JCS). Please refer also to HRB Grant Policies.

Lead Applicants based in Ireland will be required to provide additional information to the HRB at the time of submission. This will include justification for their requested budget, and clarification on deliverables assigned to the partner from Ireland. Templates requesting the information required from applicants from Ireland will be provided by the HRB.

7.2 Review Process

The Joint Call Secretariat (JCS) will check all proposals to ensure that they meet the call's formal criteria. In parallel, the JCS will forward the proposals to the national/regional funding organisations, which will perform a check for compliance with national/regional regulations.

Each proposal passing the eligibility check (JCS and country/region) will be provided to three reviewers for evaluation. The reviewers will perform the assessment of the proposal and complete a written evaluation form with scores and comments for each evaluation criterion.

Before the Peer Review Panel (PRP) meeting, each coordinator will be provided with the reviewers' assessments and will have the opportunity to respond to the reviewers' questions and comments (rebuttal stage).

During the PRP meeting, the reviewers will discuss the proposals and produce a ranking list of proposals recommended for funding.

After the PRP meeting, members of the ERA4Health Ethics and RRI Advisory Board will remotely evaluate the proposals, which are recommended for funding by the PRP and selected for funding by the CSC, for alignment with ethical norms and regulations.

Only those proposals approved by both the scientific evaluation and ethical clearance can be funded.

A final decision, based on the ranking list established by the PRP, available funding and the ethics evaluation results, will be taken by the funding organisations.

7.3 Assessment Criteria

Proposals not relevant to the call topic and objectives will not be funded, independently of their scientific quality.

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.

8 Timeframe

Date	
13 January 2023	Call Opening
18 January 2023	Webinar registration deadline
26 January 2023	Webinar for applicants
14 March 2023 @14:00	Call Closing
16 – 25 August 2023	Rebuttal stage

End October 2023	Communication of funding decisions to applicants
Jan 2024	Earliest start date for Irish partners
May 2024	Latest expected project start date

9 Contacts

For further information on the ERA4Health joint transnational call for "Increasing health equity through promoting healthy diets and physical activity (HealthEquity)" contact:

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

DLR Project Management Agency, Germany
Dr Felicitas Bosen and Dr Ann Siehoff
Email: era4health@dlr.de

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

Dr Siobhán Hackett
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[6]. 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.

[6] 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[7] and open publishing directly through the HRB Open Research platform[8]. 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[9] 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[10], 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.

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

[8] https://hrbopenresearch.org/

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

[10] 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

The following Data Privacy Notice applies:

By submitting an application, the applicants consent to the use, processing and retention of their personal data[11], in accordance with article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679) 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 Organisations relationship with them;
- analysing and evaluating the call;
- providing aggregate data to national and European surveys and analyses on the funded projects;
- and complying with audits that may be initiated by the Funding Organisations and the European Commission (or its agencies).

The members of the CSC 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).

The members of the CSC may link the data that funding recipients provide in the application with national, bibliographic or external research funding data which are 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

[11] 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, project proposals (scientific document, administrative and financial appendix).

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)[12]. 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[13].

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[14] and Retention Policies[15].

Additional guidance on Costs

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

[13] https://hrcdc.ie/

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

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

1. 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 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. 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.
2. 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. Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
3. Equipment	Funding for suitably justified equipment can be included in this section. 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.
4. Dissemination Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[16]. 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.
5. 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.

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

6. Overhead Contribution	In accordance with the HRB Policy on Overhead Usage[17], 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.

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

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

Appendix II: Resources/Useful Links

STUDY DESIGN FOR INTERVENTIONS

"Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework" by Eldridge S. *et al.*

http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0150205

"The PRECIS-2 tool: designing trials that are fit for purpose" by Louden *et al.*

http://dx.doi.org/10.1136/bmj.h2147

"A process for Decision-making after Pilot and feasibility Trials (ADePT): development following a feasibility study of a complex intervention for pelvic organ prolapse" by Bugge C *et al*.

http://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-14-353

"Developing and Evaluating Complex Interventions" by MRC, UK

www.mrc.ac.uk/complexinterventionsguidance

"Process evaluation of complex interventions: Medical Research Council guidance" by Moore GF. e*t al.*

http://dx.doi.org/10.1136/bmj.h1258

"Using natural experiments to evaluate population health interventions: Guidance for producers and users of research evidence" by MRC, UK

www.mrc.ac.uk/naturalexperimentsguidance

Consort 2010 Statement: updated guidelines for reporting parallel group randomised trials

www.consort-statement.org

SQUIRE Guidelines: provides a framework that authors can use when developing applications or writing research articles about quality improvement

www.squire-statement.org

HIQA Guidelines for the Economic Evaluation of Health Technologies in Ireland (2018)

https://www.hiqa.ie/reports-and-publications/health-technology-assessment/guidelines-economic-evaluation-health

HIQA Guidelines for the budget Impact Analysis of Health Technologies in Ireland (2015)

https://www.hiqa.ie/system/files/Guidance_on_Budget_Impact_Analysis_of_Health_Technologies_in_Ireland.pdf

HIQA Guidelines for Evaluating the Clinical Effectiveness of Health technologies in Ireland (2011)

http://www.hiqa.ie/system/files/HTA-Clinical-Effectiveness-Guidelines.pdf

STUDY REGISTRATION

International Clinical Trials Registration Platform (run by the WHO)

http://apps.who.int/trialsearch/Default.aspx

European Clinical Trials Database (EudraCT): database of all regulated clinical trials which commenced in the EU from 1 May 2004

https://eudract.ema.europa.eu/results-web/

US National Library of Medicine database: database of privately and publicly funded clinical studies – regulated and unregulated - conducted around the world

https://www.clinicaltrials.gov/

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/

CLINICAL RESEARCH INFRASTRUCTURES

All Ireland Hub for Trials Methodology Research

http://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/TheAll-IrelandHubforTrialsMethodologyResearch/

Centre for Advanced Medical Imaging, St James' Hospital Dublin

http://www.3tcentre.com/

Centre for Support and training Analysis and Research (CSTAR)

http://www.cstar.ie

Children's Clinical Research Unit

https://www.nationalchildrensresearchcentre.ie/childrens-clinical-research-unit/apply-for-support/

Clinical Research Support Unit, **Limerick**

https://www.ul.ie/hri/clinical-research-support-unit

Clinical Research Centre, Royal College of Surgeons in Ireland

https://www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/clinical-research-centre

Clinical Research Facility, University College Dublin

http://www.ucd.ie/medicine/ourresearch/researchenvironment/ucdclinicalresearchcentre/

Clinical Research Support Centre (Northern Ireland)

http://www.crsc.n-i.nhs.uk/

HRB Clinical Research Facility, Cork (HRB CRFC)

http://www.ucc.ie/en/crfc/

HRB Clinical Research Facility, Galway (HRB CRFG)

http://www.nuigalway.ie/hrb_crfg/

HRB Critical Care Clinical Trials Network (HRB Critical Care CTN)

ICC-CTN (iccctn.org)

HRB Irish Network for Children's Clinical Trials (in4kinds)

In4kids

HRB Primary Care Clinical Trials Network (HRB Primary Care CTN)

Primary Care Clinical Trials Network Ireland - HRB PC CTNI (primarycaretrials.ie)

HRB Trials Methodology Research Network (TMRN)

http://www.hrb-tmrn.ie

The National Clinical Trials Office (NCTO)

Email trials-ireland@ucc.ie

https://ncto.ie/

Wellcome Trust-Health Research Board Clinical Research Facility, St James's Hospital (WT-HRB CRF SJH)

http://www.sjhcrf.ie/

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

INCLUSION OF UNDERSERVED GROUPS IN RESEARCH

- **NIHR INCLUDE Framework** https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435
- **INCLUDE Ethnicity Framework** https://www.trialforge.org/trial-forge-centre/include/
- **Statement by the National Athena SWAN Ireland Intersectionality Working Group** on the Use of Ethnicity Categories in Irish Higher Education Intersectionality-WG-Statement-on-Ethnicity-Categories-in-Irish-HE.pdf (hea.ie)

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/