# THCS Joint Transnational Call (2023) "Healthcare of the future"

Guidance Notes

# Guidance Notes

| Key Dates & Times | |
|---|---|
| Application Open | 22 March 2023 |
| Intent to apply deadline | 23 May 2023 @13:00 |
| Application Closing Date | 13 June 2023 @13:00 |

*Your intent to apply and application must be completed and submitted through the online portal (found on the THCS call webpage). This system will close automatically at the stated deadline and timeline listed above. Applications will not be accepted without an associated intent to apply submitted by the deadline.*

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 THCS 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 Transforming Health and Care Systems (THCS), a European partnership[2] whose vision is to contribute to the transition towards more sustainable, efficient, resilient, inclusive, innovative and high-quality people-centred health and care systems that are equally accessible to all. The EU-funded THCS Partnership brings together 64 entities and funding organisations from 26 countries, with the common goal to support research and innovation for the transformation of health and care systems.

The ambition of the first Joint Transnational Call (JTC) for proposals is to identify and develop innovative solutions that can, in the future, help to relieve the pressure on health and care facilities. The call addresses the challenge presented by the increasing number of patients admitted in hospitals and/or other healthcare facilities and the need to ensure they are treated in the appropriate setting according to their respective medical condition, in a healthcare continuum that makes the best use of resources and delivers better patient satisfaction. To reach this ambition, the complementarity and coordination between inpatient and outpatient care needs to be optimised. Organisational innovations, continuity of care across all care levels, integrated care and harnessing the potential of supporting digital technologies provide a multitude of possibilities for such optimization, creating opportunities for health and care systems to reap the benefits of distributed health and care.

Collaborative transnational projects responding to the challenges and opportunities described here will be supported through this call. The goal of this call is to identify, develop and implement innovative solutions that can inform decision-making and optimise the delivery of health and care services across different settings. These solutions should aim to make health and care systems economically, socially, and environmentally sustainable, while keeping people at the centre of the care process.

The challenges are complex and can be addressed with a wide variety of Research and Innovation (R&I) projects and concepts. These include applied, innovative research as well as the development of strategies, testing, and implementing and assessing interventions and solutions in the different partner countries and in different health and care contexts and settings. Suggested research and innovation topics are further described below.

[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.

# 2 Aim and Objectives

This first call aims to:

1. Provide the necessary knowledge to build the health and care of the future. This includes addressing several dimensions of health and care systems such as quality, safety, equity, efficiency, effectiveness, accessibility, sustainability, economy, ethics and resilience in reorganised health and care settings. By providing this knowledge, the call aims to support the development of new and innovative solutions that can address the current and future challenges facing health and care systems.

2. Support the implementation of innovative solutions on a larger scale. This includes identifying and promoting the adoption and transferability of evidence-based and successful practices that have already been proven to be effective in some contexts in addressing the challenges facing health and care systems. With research and innovation supporting the implementation of these existing solutions, the call aims to accelerate the pace of change and make a positive impact on health and care systems in a more efficient way.

# 3 Scope of Call

The JTC 2023 envisages proposals addressing solutions for seamless integration of health services in different settings in which health and care is delivered and received, locally, regionally, at home or in specialised hospitals, and in different contexts. Proposals should identify and describe the health and care settings where particular needs can be best addressed. Proposals can focus on one or more intervention areas (i.e., non-communicable and communicable diseases (NCDs and CDs), cancer etc.)

Proposals should aim at presenting a clear vision of the future role, mission, and activities of health and care organisations within the context of new and evolving care settings and determining the most appropriate roles in that new context.

Applied research, and implementation research, developing, piloting, and testing are within the scope of the call. Projects demonstrating proof of concept(s), validation of concepts or solutions, and demonstrations of solutions in relevant health and care settings, replication in other settings are also within scope.

## 3.1 Essential elements

The research and innovation activities should provide a broad range of knowledge, models, and solutions, while maximising the service coverage, ensure the best care pathway, and also ensuring safety, quality, and equal access to health and care. Proposals may address several dimensions of health and care systems.

Proposals must address the economic and social impact of the proposed models/solutions/approach and show how the project will be linked to the policy context and wider eco-systems.

Applicants are required to describe how end-users and other stakeholders (e.g. policymakers, healthcare professionals, informal carers, patient representatives and voluntary organisations/NGOs)

are involved in the planning and implementation of the project, in dissemination activities and in the planned utilisation of the results.

## 3.2 Other elements to consider

Examples of research and innovation areas particularly relevant to this call can be found in the core THCS call text, section 4.3.

## 3.3 Excluded approaches

Proposals will be rejected if they:

1. Have a predominantly pre-clinical / bio-medical component.
2. Are purely epidemiological studies mapping the extent of and causal factors behind illnesses, without a focus on solutions, models or implementation in the health and care systems.
3. Solely concern social / welfare services and do not address issues in the health and care services.
4. Solely concern the development of new technological solutions, without a focus on integration of the solutions, models or implementation in the health and care systems.

***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 THCS 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 12–36 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 (€19,000 per annum) and fees (EU rate only)

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

c) Direct running costs (including travel, mobility costs, 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 costs.**

Funding available is inclusive of overheads and pension contributions.

Note: The THCS 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 between December 2023 and May 2024.**

# 5 Eligibility Criteria

Please refer to Section 3 for excluded approaches and topics.

**This call is not open for Host Institutions in Northern Ireland.**

All Annexes referenced herein can be found in the core THCS call text.

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

## 5.1 Consortium Composition

Only transnational projects will be funded. **There is a partner search tool available for this call: https://partfinder.ncbr.gov.pl/**

Each project proposal must include:

- One project coordinator who will represent the consortium externally and will be responsible for its internal management and reporting. Coordinators must be eligible for funding by one of the funding organisations listed in Annex I (core call text). For coordinators based in Ireland, this is the HRB. The same applicant may only be project coordinator of ONE project proposal submitted to this call.
- At least three independent legal entities (partners), including the coordinator, from at least three different countries participating in the THCS JTC 2023.
- No more than three consortium partners can be from the same country.
- The total number of partners in a consortium is limited to nine, excluding collaborators, i.e. partners participating with their own expenses and therefore fully self-financed.
- No more than two self-financed partners (collaborators) can participate. The inclusion of collaborators is optional. See 5.1.2 for further information.

### 5.1.1 Lead Applicants based in Ireland

***Note that HRB use the term 'Lead Applicant' to refer to a coordinator or partner applying for HRB funding.***

The following will apply to partners seeking HRB funding – i.e., Lead Applicants based in Ireland.[3] 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.

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.

***Applicants must demonstrate that they meet the eligibility criteria by 1) including the relevant information in the application form (CV) or 2) by submitting additional documentation via email (eujointprogrammes@hrb.ie) to the HRB in advance of call submission deadline.***

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

[3] 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.

### 5.1.2 Collaborators

The inclusion of collaborators (fully self-financed partners) is optional and is limited to two per consortium.

Collaborators cannot be project coordinator and must demonstrate a clear added value in the project. Collaborators may only participate in project consortia if they demonstrate, at the time of the proposal submission, that their financial and human resources are secured for the entire project period and will be available at the start of the project.

# 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[4].

**Host Institution Letters of Support** must be provided for **(1) all Lead Applicants in a contract position and (2) Adjunct Professors not directly employed by the HI.** These must be emailed to eujointprogrammes@hrb.ie before the proposal submission deadline. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information;

- Case (1): [*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 are fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team.
- Case (2): [*Host Institution - insert name*] confirms that [*applicant - insert name*] has the authority and resources allocated to hold and manage a grant under their Adjunct status for at least the duration of the award.

# 7 Application, Review Process and Assessment Criteria

## 7.1 Application

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

There will be a one-stage application procedure for joined applications **preceded by a mandatory Intent to Apply**. One Intent to Apply and one full proposal document shall be prepared by the Project Partners of the project consortium and must be submitted by the Project Coordinator through the THCS Partnership Online Submission System (found on the THCS call webpage). These must be submitted no later than:

- Intent to Apply: 13:00 GMT on 23 May 2023
- Full proposal: 13:00 GMT on 13 June 2023

**No other means of submission will be accepted.**

For further details, please refer to the respective submission forms available through the guidance document on the THCS call 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 upon submission of the proposal. This will include justification for their requested budget, and clarification on deliverables assigned to the partner from Ireland. Templates requesting this information will be provided by the HRB after submission of the Intent to Apply or before, upon request.

## 7.2 Review Process

There are four steps of review:

1. Formal check of proposals: The Joint Call Secretariat and Call Steering Committee (CSC; funding bodies) perform initial checks to confirm compliance with the call criteria and the eligibility of partners.
2. Peer-review of proposals: Each proposal will be reviewed by three reviewers, who will each provide a written evaluation form with scores and comments.
3. Rebuttal stage: Each coordinator is provided with the assessment and given one week to respond to the comments or questions from the assessments.
4. Peer Review Panel: Reviewers form a Peer Review Panel (PRP) which will meet to discuss the full proposals, produce and assessment report and supply a ranking list of proposals recommended for funding.

Following the Peer Review Panel, the CSC meet to make final decisions on funding, prioritising higher-ranked proposals, taking into account other priorities (listed in section 8.8 of the core call text) and maximising use of the available budget.

For full details please refer to the core call text.

## 7.3 Assessment Criteria

The number of participants and their research contribution should be appropriate for the aims of the transnational research and innovation 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.

Proposals are assessed for scope and provided a mark (from 0–5) for each criterion of excellence, impact and implementation.

# 8 Timeframe

| Date | |
|---|---|
| 22 March 2023 | Call Opening |
| 23 May 2023 @13:00 | Intent to Apply deadline (**mandatory)** |
| 13 June 2023 @13:00 | Call closing |
| Q4 2023 | Communication of funding decisions |
| Dec 2023 | Earliest start date for Irish partners |
| May 2024 | Latest expected start date for consortia |

# 9 Contacts

For further information on the Transforming Health and Care Systems Joint Transnational call for "Healthcare of the future" contact:

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

ZonMw, Netherlands
E-mail: thcs@zonmw.nl

**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[5]. 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.

[5] 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[6] and open publishing directly through the HRB Open Research platform[7]. 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**[8] 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[9], 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.

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

[7] https://hrbopenresearch.org/

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

[9] 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), 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;
- Complying with audits that may be initiated by the funding organisations and the European Commission (or its agencies).

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 regional/national, bibliographic or external research and innovation 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 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)[10]. 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[11].

## 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[12] and Retention Policies[13].

## Additional guidance on Costs

| **Personnel costs** | **Must be listed for each salaried personnel under each of the following subheadings (a-c):** |
|---|---|
| **a) Salary** | Gross Annual Salary (negotiated and agreed with host institution). Applicants should use the IUA Researcher Salary Scales. |

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

[11] https://hrcdc.ie/

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

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

| | |
|---|---|
| | 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.<br><br>Applicants should include annual pay increments for staff and related costs (pension contribution, employer's PRSI contribution, and overhead contribution) in the budget.<br><br>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.<br><br>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.<br><br>Exceptions apply where Circular letter 6/2007 applies.[14] |
| **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.<br><br>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'.<br><br>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. |

[14] 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.

| | |
|---|---|
| | The following costs are ineligible and will not be funded: animal study costs, inflationary increases, cost of electronic journals.<br><br>Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs. |
| **Equipment** | Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €10,000. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e., overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified. All costs must be inclusive of VAT, where applicable. |
| **Dissemination Costs** | Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan, as well as costs related to data sharing.<br><br>Please refer to the HRB policy on Open Access to Published Research[15]. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary).<br><br>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.<br><br>Conferences: We envisage that conference costs will be typically around €500/year for national conference and €1,500/year for international conference. |
| **FAIR Data Management Costs** | Costs related to data-related and data management activities in line with best practice of data management and stewardship and the FAIR principles incurred during the lifetime of the project. Please see table below for further guidance. |
| **Overhead Contribution** | In accordance with the HRB Policy on Overhead Usage[16], 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.<br><br>The following items are included in the overhead contribution: recruitment costs, bench fees, office space, software, contribution to gases, bacteriological |

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

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

| | |
|---|---|
| | 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* |

# 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

## 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/