

ERA4Health Joint Transnational Call (2024) "Modulation of brain ageing through nutrition and healthy lifestyle (NutriBrain)"

Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	3 November 2023
Application Closing Date	15 January 2024 @15:00 GMT

Applications must be completed and submitted through the <u>relevant submission system</u>, 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 <u>ERA4health</u> <u>NutriBrain call webpage</u>, and the HRB FAQ for this call on the HRB call website.

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1 Introduction

The Health Research Board (HRB) Strategy (2021-2025)¹ sets out a lead role of the HRB to invest in research that delivers value for health, the health system, society, and the economy, as well as to foster and enhance European and international coordination, collaboration and engagement. The HRB works closely with European partners to address Europe's most pressing challenges. In 2022, the HRB joined a new initiative named ERA4Health, a European Partnership² whose vision is to foster a European Research Area for health. The EU-funded ERA4Health Partnership brings together 33 partners and 27 funding organisations from 22 countries, with the common goal of fostering high-impact translational research for addressing public health needs.

The global burden of neurodegenerative diseases is predicted to triple by the year 2050³. Increased lifespan, in combination with environmental and lifestyle modifications, is among those factors responsible for the increased prevalence of cognitive disorders of different severity, from mild cognitive impairment (MCI) till overt dementia (such as Alzheimer's disease). Due to demographic changes in Western societies, age-related diseases such as dementia are assuming a societal challenge in terms of public health and health care. In addition, maintaining cognitive abilities in old age enables people to remain independent for as long as possible and increases the number of years with a high quality of life.

To date, there is no proven disease-modifying treatment for cognitive impairment during ageing, so the main focus is on prevention and early detection. Epidemiological studies suggest that obesity, inadequate nutrition, protein energy malnutrition (PEM), poor sleep, and physical inactivity increase the risk of cognitive impairment, although there is still limited evidence of how better nutrition and increased physical activity could slow down brain ageing and lower the risk of cognitive impairment. Thus, increasing knowledge on promoting changes in lifestyle in pre-symptomatic and predementia stages, implemented in evidenced based multimodal interventions, are highly needed since they may have the potential for delaying a high proportion of dementia worldwide.

Outputs from this call are expected to pilot test interventions based on the existing evidence in the literature or to upscale existing pilot interventions that will help to lower the risk of cognitive impairment manifestations related to a pathological brain ageing. This will include new insights on how lifestyle in general and in particular dietary choices, physical activity, sleep, social interaction, and stress may influence the trajectory of brain ageing that will underpin the development of new products, services and policies for middle-aged and older people. In the longer-run, improved brain ageing is expected to increase independence and to lower the individual, family, and social services of the burden and the expenses associated with age-related cognitive disorders. From a translational point, this will fill the gap between the scientific evidence on the protective role of healthy lifestyle factors and the current lack of systematic application in clinical, healthcare-related settings and active ageing policies.

¹ <u>https://www.hrb.ie/strategy-2025/</u>

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.

³ Estimation of the global prevalence of dementia in 2019 and forecasted prevalence in 2050: an analysis for the Global Burden of Disease Study 2019 GBD 2019 Dementia Forecasting Collaborators, Lancet Public Health 2022; 7: e105–25 Published Online January 6, 2022 https://doi.org/10.1016/ S2468-2667(21)00249-8

Major changes since the last round

In recognition of the rising costs of research, the overall budget has been increased. Please refer to Section 4 for details.

This scheme is not framed as a training initiative for PhD candidates and, as the maximum duration of projects (three years) is less than the HRB standard for PhD funding (four years), we will be unable to support PhD student stipends or fees for this call. Where candidates for a Master's degree are proposed to work on projects, Lead Applicants must show evidence of careful consideration ensuring a good training experience for the Master's candidate.

2 Aim and Objectives

The aim of the call is to support transnational research projects that focus on the improvement of cognitive brain ageing through nutrition and other lifestyle factors. Thereby it enables scientists from different countries to build a valuable collaboration on interdisciplinary research projects based on complementarities and sharing of expertise in the field of brain ageing, its related disorders, nutrition and lifestyle factors.

Research projects should gain further insights into the modulation of brain aging by lifestyle factors and/or pilot test interventions based on the existing evidence in the literature or upscale existing pilot interventions that will help to lower the risk of cognitive impairment manifestations related to a pathological brain ageing.

3 Scope of Call

At least one of the following lifestyle factors should be investigated: nutrition (particularly improvements in dietary pattern), physical activity, sleep pattern (quantity, quality and timing), social interaction and stress.

Researchers should apply a perspective of prevention and public health, taking into consideration large population groups such as age cohorts or relevant subgroups.

Proposals may include one of the following approaches, such as:

- Pilot test interventions that will help to lower the risk of cognitive impairment manifestations related to a pathological brain ageing
- Upscale existing pilot interventions that will help to lower the risk of cognitive impairment manifestations related to a pathological brain ageing

Proposals may be supplemented by one of the following approaches, such as:

- Mechanistic / experimental research focusing on how specific lifestyle factors influence brain ageing;
- Translational research that will establish proof of concept, in order to support the development of effective health-improvement strategies and/or solutions to promote a healthy brain.

In addition, the following points should be considered:

- Research proposals may focus on specific population groups, e.g., those living with obesity and/or sarcopenia or with specific phenotypes, who may benefit from particular dietary and/or physical activity and lifestyle interventions, but can also focus on broader populations groups.
- For projects focussing on the prevention of cognitive impairment before the onset of clinical symptoms, the target group is not necessarily elderly, but may also include adults of other age groups.
- Applicants should make use of existing biobanks and cohorts, if applicable. Otherwise, it should be explained why existing cohorts are not used.
- Applicants need to define the standardized approach for sample collection, isolation and analysis
 methods and explain the tools they plan to use to measure nutritional status, dietary
 consumption, eating behaviour, other lifestyle factors and cognitive decline as well as cognitive
 impairment through ageing in their proposals.
- Where relevant, investigations should employ existing biomarkers/surrogate outcomes that relate strongly to the risk of cognitive impairment. These include biomarkers related with the gut-brain axis, neuroendocrine signalling, and microbiota, especially those easily, affordable and feasible to obtain. Furthermore, other more sophisticated biomarkers derived from cerebrospinal fluid and image should be considered. The development of new biomarkers is not within the scope of the call.
- There may be opportunities to also use omics approaches, brain imaging, microbiota study linked, digital health data to get robust measures of diet, nutritional status, physical activity, sleep, social interaction, stress in well-characterised prospective cohort studies in adults and older people.
- The project should be consumer-centred: the involvement of the target population in the research is strongly encouraged at all stages of research design, implementation, analysis and dissemination. Research proposals are encouraged to also apply participatory methods, participatory agenda settings, informal settings, crowdsourcing data collection.
- Proposals should consider potential moderators of effects such as age, sex, gender and ethnic or other demographic features/differences in the respective research approaches.
- Where relevant, emerging model systems should be preferred to animal models. Research may make use animal models only for investigations that are impractical or unethical in humans and they must be justified. In this case, it is important to have mechanistic studies combined with observational research emphasising humans and it's needed a clarification on how the observations of animal models translate to humans (back and forth translation).
- The impact indicators should be identified at the project proposal stage.
- Applicants are encouraged to consider the gender balance in the composition of the consortia and to balance the responsibilities between them.
- The proposed research should not overlap with previous studies funded under the JPI HDHL and JPND calls or collaborations should be established.
- Early Career Scientists (Master students, PhD students and post-docs) are encouraged to participate in the consortium.

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

Proposals should follow the principles of Responsible Research and Innovation (RRI). All consortia should demonstrate a commitment for investigating and addressing social, ethical, political, environmental or cultural dimensions of the proposed research. The proposal template further elaborates on this and how RRI dimensions can be approached.

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 2020/Europe⁴).

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 application potential to benefit of patients and citizens.

Furthermore, additional elements need to be considered in the application:

- If appropriate: the design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and should be part of the proposal.
- In case of an exploratory animal/interventional study, a detailed description is required as part of the full proposal application form (requirements are included in the Guidelines for Pre-clinical and small-scale clinical studies up to phase 2). The review panel will scrutinize this information as part of the formal evaluation criteria (1-Excellence) of full proposals. Assistance for provision of the information on experimental design can be found in the general <u>ARRIVE guidelines</u>.

3.1 Excluded approaches and topics

Proposals that relate purely to the study of pathomechanisms are not eligible for funding in this call.

In addition to the above, 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.

Please note that additional conditions might apply to other partners at a national level (see <u>Annex I</u> of the central call text).

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

⁴ <u>https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm</u>

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 <u>Annex I</u> of the central call text).

For applicants based in Ireland, the HRB will provide funding for projects up to a maximum of €330,000 direct costs per award. Additional funding of up to €75,000 direct costs will be made available for coordination activities (cannot be used to cover equipment and consumables) bringing the total to €405,000 direct costs for coordinators. The maximum total award, including overhead contribution, will be €430,000, for a partner and €530,000 for applicants who take on the role of coordinator.

The HRB plans to commit up to €530,000 to the ERA4Health JTC2024 awards. 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. Salary related costs for Lead Applicants in contract positions up to a maximum of 0.5 FTE protected time for research funded by HRB for up to three years.
- b) Direct running costs (including travel, mobility costs, patient-related costs and costs to support interventional studies)
- c) PPI costs
- d) Small equipment costs (not expected to exceed €10k)
- e) 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.
- f) Dissemination and knowledge exchange activities (including dissemination-related travel)
- g) Overheads contribution

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

Funding available is inclusive of overheads and pension contributions.

Note: The ERA4Health award will not fund PhD stipends and fees, nor 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.

Projects are expected to start between December 2024 and May 2025.

5 Eligibility Criteria

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

Please also refer to Section 3.1 for excluded approaches and topics. All Annexes referenced herein can be found in the <u>central ERA4Health call text</u>.

Please note that additional conditions might apply to other partners at national level (see Annex I).

5.1 Consortium Composition

Only transnational projects will be funded. **There is a partner search tool available for this call:** <u>https://era4health.eu/partner-search/</u>.

The following conditions apply to the composition of consortia:

- There must be a minimum of three and a maximum of five eligible partners from at least three different countries participating in the call.⁵
- 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 countries: Estonia, Lithuania, Romania and Slovakia.
- No more than two eligible partners from the same country participating in the call will be accepted within one consortium.
- There is a maximum of two collaborators per consortium (refer to section 5.1.3 below)

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.⁶ If there is more than one Irish partner/coordinator and they are based in different Host Institutions (see Section 6), they must apply as separate partners.

Where more than one Irish coordinator/partner exists, each must meet the Lead Applicant eligibility criteria. However, the HRB will only contract with the Host Institution of one Lead Applicant (this must be the coordinator if an Irish coordinator exists).⁷ This Lead Applicant will serve as the primary point of contact for the HRB during the review process and on the award, if successful. They 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. Where applicable, they

⁵ Austria, Belgium, Canada, Denmark, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Norway, Poland, Romania, Slovakia, Spain, Switzerland, Taiwan, The Netherlands, Türkiye.

⁶ 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.

⁷ For administrative purposes, the second partner will be recorded in HRB systems as a Co-Applicant.

must distribute the funds appropriately to the second Irish partner via collaboration and/or consortium agreements.

Partners seeking HRB funding must belong to categories A (Academia) or B (Clinical/public health sector). Categories C (Enterprise) and D (Operational stakeholders) are not eligible for HRB funding.

All partners 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 (an accompanying letter of support is required in these cases, as well as in the case of contract positions – see Section 6 below).

OR

Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission (an accompanying letter of support is required in these cases – see Section 6 below).

They **<u>must</u>** 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 peerreviewed 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 completing the <u>Lead Applicant</u> <u>eligibility form</u> by the submission deadline.

Each applicant can submit only one application if they are a coordinator or up to two proposals as partner.

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

As signatory of the DORA Declaration,⁸ the HRB is committed to supporting a research environment where importance is placed on the intrinsic value and relevance of research and its potential impact in society.

5.1.2 Collaborators

Collaborators are self-funded partners: *i.e.*, partners from non-funding countries⁷ or partners that are not fundable according to national/regional regulations of the participating funding organisations).

The following conditions apply for collaborators:

- They must provide clear added value for the research project. This should be demonstrated in the application.
- They must 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 preproposal/ full proposal.
- A collaborator cannot be work package leader.

5.1.3 Funded Personnel

Alignment between personnel requested and the proposed project should be demonstrated. Roles and responsibilities of funded personnel must be differentiated and clear.

This scheme is <u>not</u> framed as a training initiative for higher degree candidates. It will not cover costs for PhD students. Where candidates for a Master's degree are proposed to work on projects, Lead Applicants must carefully consider:

- The complexity, scale, objectives, and dependencies of the project.
- The suitability of such project in terms of delivering a clearly identifiable original research project or the potential difficulties in clustering various pieces of work packages for a Master's thesis. The skills, expertise and experience level required to carry it out.
- Any requirements and/or restriction relating to the Master's candidate's registration with the Host Institution, and this should be accounted for when determining the start date of the award.

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 <u>approved</u> HRB Host Institution no later than two calendar months before the

⁸ Home | DORA (sfdora.org)

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 website⁹.

Please note that this call is not open to HIs from Northern Ireland.

Host Institution Letters of Support must be provided for (1) all named 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 pre-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

There will be a two-stage application procedure for joined applications. One joint proposal document (in English) shall be prepared by the partners and must be submitted by the Coordinator in electronic format no later than 15:00 GMT on 15 January 2024 via the <u>electronic submission system</u>. **No other means of submission will be accepted.**

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

Lead Applicants based in Ireland will be required to provide additional information to the HRB at the time of submission of full proposals. Applicants must demonstrate that they meet the eligibility criteria by completing the <u>Lead Applicant eligibility form</u> by the pre-proposal submission deadline.

At Full proposal, applicants must submit a 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.

⁹ <u>http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/</u>

7.2 Review Process

The following are the main steps in the two-stage review process:

- 1. Formal check of pre-proposals: The Joint Call Secretariat (JCS) and Call Steering Committee (CSC; participating funding bodies) perform initial checks to confirm compliance with the call criteria and the eligibility of partners.
- 2. Peer-review of pre-proposals: Each proposal will be reviewed by three reviewers, who will each provide a written evaluation form with scores and comments.
- 3. Invitation to second stage: CSC members will decide which proposals will be invited to submit a full proposal based on the reviewers' recommendations and to ensure a reasonable balance of requested and available national/regional budgets.
- 4. Steps 1 and 2 are repeated for full proposals. Any fundamental change between pre- and full proposals must be communicated to the JCS and to the national/regional funding organisations involved; *e.g.*, concerning the composition of the consortium, the objectives of the project or the requested budget. In exceptional cases, these changes may be admitted if detailed justification is provided and if they are accepted by CSC.
- 5. Rebuttal stage: Each coordinator is provided with the assessment and given the opportunity to respond to the comments or questions from the assessments.
- 6. Peer Review Panel: Reviewers meet to discuss the full proposals and produce a ranking list of proposals recommended for funding.

Following the Peer Review Panel, the CSC meet to make a final decision, based on the ranking list established by the PRP, available funding and the ethical clearance.

For full details please refer to the <u>central call text</u>.

7.3 Assessment Criteria

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.

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

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

Please refer to the central call text for information on the redress (appeals) procedure for this call.

8 Timeframe

Date	
03 November 2023	Call Opening
10 November 2023	Information webinar (14:00–16:00 GMT)
15 January 2024 @15:00 GMT	Call Closing – pre-proposals
27 March 2024	Invitation for full proposal
27 May 2024 @15:00 GMT	Call closing – full proposals
12–23 August 2024	Rebuttal stage
Mid-October 2024	Communication of funding decisions
December 2024	Earliest start date for Irish partners
May 2025	Latest expected start date for consortia

9 Contacts

For further information on the ERA4Health call for "Modulation of brain ageing through nutrition and healthy lifestyle (NutriBrain)" contact:

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

Italian Ministry of University and Research Dr. Aldo Covello and Dr. Sara Cella E-mail: <u>nutribrain@mur.gov.it</u>

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

Dr Siobhán Hackett Email: <u>eujointprogrammes@hrb.ie</u>

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 Trials Methodology Research Network (HRB-TMRN), 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.

Patient, Carers and Public Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public and patients in the research that we fund¹⁰. 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 as participants in research.

PPI represents an active partnership between members of the public and patients 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.

¹⁰ 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 or patients 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.

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 <u>open research¹¹</u> and open publishing directly through the <u>HRB Open</u> <u>Research platform¹²</u>. The HRB is driving the making of research data **FAIR** (**F**indable, **A**ccessible, Interoperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles¹³ 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 data¹⁴, 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.

¹¹ http://www.hrb.ie/funding/policies-and-principles/open-research/

¹² <u>https://hrbopenresearch.org/</u>

¹³ <u>https://www.nature.com/articles/sdata201618</u>

¹⁴ 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,¹⁵ 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

¹⁵ Last name, first name of the researchers, date of birth, professional contact information, degree(s), position (current and previous), fields of activity, place of work, organisation, address(es), curriculum vitae, ORCID number, name and reference of projects, pre-proposals, project proposals (scientific document, administrative and financial appendix).

including PI, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended, we will continue to keep your information on file (in accordance with HRB policies) to allow us to evaluate the outcomes, outputs and impacts of HRB investment in your research.

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

The Health Research Regulations

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

Research on Research

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

Privacy Policy and Retention Policy

To understand why HRB collects the information we collect and what we do with that information, please see our Privacy¹⁸ and Retention¹⁹ Policies.

Additional guidance on Costs

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

¹⁷ https://hrcdc.ie/

^{18 &}lt;u>https://www.hrb.ie/about/legal/privacy-policy/</u>

¹⁹ https://www.hrb.ie/fileadmin/user upload/HRB Document retention policy..docx

Note that the below categories are used by HRB for contracting and may not match the central application. Please include these in the most appropriate heading within the application, and ensure that your budget submitted to HRB (at full proposal stage) aligns overall with the application. All costs should be in line with Host Institution policies.

Personnel costs	Must be listed for each salaried personnel under each of the following
	subheadings (a-c):
	Gross Annual Salary (negotiated and agreed with host institution). Applicants
	should use the <u>IUA Researcher Salary Scales</u> .
	Applicants are advised that public sector pay increases to 1 st October 2023
	(inclusive) have been agreed. Please apply a salary contingency of 3% per
	annum from 1 st October 2024. Please note this contingency should be applied
	cumulatively on 1 st October year on year.
a) Salary	
a, Salary	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.
	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).
c) Employer Pension	
Contribution	If applicable, state the amount of employer contribution based on the pro rata
	salary and note the % of pro rata salary used to calculate this for reference.
	Exceptions apply where Circular letter 6/2007 applies. ²⁰
	PhD Student Stipends are not supported under this scheme. A stipend for
Student Stipend	academic based post graduate MSc candidates is allowed in line with current
	government guidelines as a flat rate, which is currently €19,000 per annum for
	up to two years.
	The stipend is tax exempt and in no circumstances the stipend can be used to
	support postgraduate fees.
	Please note that the HRB does not support stipends different than the current
	national rate (€19K).

²⁰ Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.

	PhD Student Fees are not supported under this scheme. The HRB support a maximum contribution to postgraduate MSc fees of €5,500 annually for
	individuals registered for a higher degree for up to two years.
Student Fees	Where the rate of the final year is reduced in line with the Institutional policy the HRB reserves the right to recover the unspent fees.
	Please note:
	 Postgraduate fees are paid at EU level only.
	The HRB does not support fees for MD degrees.
	For all costs required to carry out the research including materials and
	consumables, survey costs, travel for participants, transcription costs, data
	access costs etc. Maintenance costs of animals are allowed for pre-clinical animal models
	only. ²¹
	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'.
Running Costs	Travel, events and subsistence costs that are associated with running the project or coordinating the consortium should be included here. Those associated with dissemination should be included under Dissemination Costs.
	Costs associated with PPI should be included in a separate section, below.
	The following costs are ineligible and will not be funded: PhD stipends and fees, external training courses/workshops, inflationary increases, cost of electronic journals, maintenance contracts on equipment, hospitality and entertainment costs, technology transfer or patent costs, conference costs, journal subscriptions, relocation expenses.
	Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
	All PPI-related costs for the grant (except salaried personnel), such as but not limited to:
DDI coste	Compensating PPI contributors for their time (for example for time
PPI costs	spent reviewing material/ participation in advisory groups)
	Travel expenses for PPI contributors
	Training in PPI in research

²¹ The maximum HRB allowable per diem rates for the maintenance of the most common strains of small animals are: mice (≤ 0.50), other laboratory rodents (≤ 1) and rabbits (≤ 2). All per diem rates are inclusive of VAT. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis.

	Costs associated with PPI contributors attending conferences,
	workshops or training
	PPI event facilitator costs
	Room hire for PPI events/meetings.
	Hospitality for PPI events/meetings
	Companionship or childcare costs for PPI contributors while attending
	events, meetings, etc.
	Note:
	• PPI participants supported by salaries, should be listed and justified
	under the personnel heading.
	 All costs should be in line with Host Institution policies.
	Funding for suitably justified equipment can be included in this section.
	Equipment costs cannot exceed €10,000 (including VAT). All costs must be
	inclusive of VAT, where applicable.
	The HRB will not fund stand-alone computer and laptop related accessories,
	such as docking stations, monitors and keyboard as these are considered
	standard piece of office equipment that should be available at the Host
	Institution, and are supported by overheads.
Equipment	
	Dedicated laptops that are required specifically for the project because of the
	mobile nature of the research, will be considered where appropriately
	justified. The maximum amount allowed for a laptop is €1,200, including VAT if
	applicable. Individuals requesting a high spec computer will be required to
	submit a quotation to the HRB at contracting stage. Clear justification and
	rationale for the type of computer and costs requested must be provided in all cases.
	The HRB will contribute to costs associated with publication of results,
	seminar/conference/workshop 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. ²² Please
	list dissemination costs under the following categories: publications,
Dissemination Costs	conferences, other activities (expanded as necessary).
	Publications: HRB grant holders are required to ensure that open access to all
	peer-reviewed scientific publications relating to the output of their project are
	in line with the HRB Policy on Open Access. ²³
	Conferences/Other events: Events, travel and subsistence costs that are
	associated with running the project and/or coordinating the consortium
	······································

²² http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/

²³ <u>https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/open-access/</u>

	should be listed in Running Costs (or PPI Costs if relevant) and costed as
	appropriate (the below limits do not apply).
	Costs are calculated on a lump sum basis of $\leq 1,500$ per person (Grant holder and/or research personnel employed in the Grant) for the total of one year less than the overall term of a Grant. Additionally, these costs can be cumulative during the award, which means the expenditure does not have to be at the maximum of $\leq 1,500$ /year. For example, for a project with a three-
	year duration: costs for two years can be requested, up to €3,000 per person, which could be budgeted as €1,500 per year 2 and 3, €500 in year 2 and €2,500 in year 3, or €3,000 in year 3, etc.
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, ²⁴ 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. This should be calculated and included in your application (note the maximum budget, including overheads, is €430,000 for partners and €530,000 for coordinators). It will be finalised by HRB staff at pre-contracting stage. 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

²⁴ http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-usage-of-researchoverheads/

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. et 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/guidelineseconomic-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 Technologi es 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-forsupport/

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/clinicalresearch-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/

PATIENT, CARERS AND PUBLIC 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-forapplicants-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

The Involvement Matrix: A tool for researchers/project leaders to promote collaboration with patients in projects and research.

https://www.kcrutrecht.nl/involvement-matrix/

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-reviewcenter-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 SHARING 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-hioa-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-hioa-data-mgt_en.pdf

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/