HRB Postdoctoral Fellowships: Clinician Scientist Fellowships (CSF) 2023

Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	06 December 2022
Application Closing Date	02 March 2023 @13:00

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie), and this system will close automatically at the stated deadline and timeline listed above.

**Prior to final submission to the HRB, all applications must first be reviewed and approved within GEMS by the authorised approver at the Host Institution (HI) as listed in the application form. It is critical therefore that applicants leave sufficient time in the process for the Research Office (or equivalent) in their nominated HI to review, seek clarifications and approve applications prior to the final submission date. This may involve being aware of and complying with any internal HI deadlines for review and approval, distinct from the HRB deadline.*

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1 Introduction

The Health Research Board (HRB) Strategy (2021-2025: Health research – making an impact)[1] highlights six strategic objectives for the HRB over the next five years, including the building of a strong and supportive environment for health research in Ireland. Within this objective, the HRB is committed to investing strategically in research leadership and building a vibrant community of health and social care researchers from different professions, backgrounds, and research interests, and working in and across a range of settings including universities and TUs, hospitals and primary, community and social care settings.

This Postdoctoral Fellowship Scheme 'Clinician Scientist Fellowships' (CSF) is part is part of a broader suite of HRB career supports[2] and is targeted at health and social care practitioners involved in the delivery of patient or social care, who have a PhD (or PhD equivalency) and wish to pursue a combined clinical and research career.

Studies have shown that health services that are more research-active tend to have lower mortality rates, greater organisational efficiency, better staff retention and higher patient and staff satisfaction. Additionally, the literature is clear that research driven by or including clinically active investigators results in improved translation of results and better patient outcomes. Clinician researcher capability therefore is a key target for capacity building.

This is the second round of this call with five awards made in 2020 and up to ten new awards envisaged in this round.

2 Aim and Objectives

The **aim** of the CSF scheme is to provide opportunities for talented **health and social care practitioners** involved in the delivery of patient or social care, who have a PhD (or PhD equivalency) and wish to pursue a combined clinical and research career.

For the purposes of this call, a **clinician scientist** is defined as a health and care practitioner who is trained in both research and a (regulated) clinical profession and conducts research embedded in a practice role.

The **main objectives** are to:

1. Support health and social care practitioners to consolidate their research skills and expertise post-PhD and to progressively develop themselves as more independent clinician scientists[3]
2. Support researchers to conduct and manage health and social care research projects that are applied and aimed at finding practical solutions to specific problems or evidence gaps.

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

[2] An overview of funding schemes along the HRB research career path for academic-based researchers and health care practitioners can be found Appendix II.

[3] For researchers with greater levels of post-doctoral experience, they should enquire about the HRB Emerging Investigator Awards Scheme.

3. Provide funding for the prospective fellow and the proposed project, but also to support them to enhance their development and growth as a researcher and as a research manager.
4. Enable the prospective fellow to gain experience of working with academic partners and knowledge users in relevant policy and/or practice organisations.
5. To provide fellows with direct experience in the conduct of health research projects that reduce the gap between research findings and clinical practice and/or health policy, and which ultimately impact on health outcomes.

It is expected that during the awards the fellows will:

- Deepen existing and or establish new collaborations and partnerships, including with knowledge users in a position to influence policy and practice
- Develop clear, independent thinking
- Strengthen their research experience
- Broaden their horizons
- Learn new research skills and methodologies
- Manage an award in their own right.

Ultimately, the fellowship should create more independent researchers who can competitively apply to more advanced funding schemes.

3 Scope

The scheme will support fellows to advance **applied health and social care research** projects where specific problems or evidence gaps are documented and where the project is focused on practical solutions.

The case for the questions posed and the related methodology, partners and knowledge users must be clearly and convincingly set out in the application form.[4]

In line with the strategic remit of the HRB, research projects are welcome spanning the areas of clinical research, population health research and/or health services research. For the avoidance of doubt, these are defined below:

Clinical research

Research with the goal of improving the diagnosis and treatment of disease and injury and of improving the health and quality of life of individuals as they pass through normal life stages. Clinical

[4] The case for the proposed applied project should summarise where the need is documented (e.g., Department of Health or HSE Strategy, WHO, other). In addition, it is expected that that evidence supporting the case for the project has been gathered systematically, i.e., a systematic review or other evidence synthesis formats. Anecdotal evidence or simple literature overviews are not considered sufficient.

research is conducted on or for the treatment of patients and involves direct participation of patients and healthy subjects and/or their samples and/or their data.

Health services research (HSR)

Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of healthcare and ultimately health and well-being.

Population health research (PHR)

Research with the goal of improving the health of the population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status or through the identification of effective interventions for improving health status and reducing health inequalities.

This scheme will not fund:

- Basic biomedical research.
- Research involving cell lines, animals, or their tissue.
- Pre-clinical studies, which involve the evaluation of potential therapeutic interventions in cells lines, animals or in human samples when the primary outcome is exploratory.
- Applications seeking to evaluate a clinical trial or other intervention. For trials and evaluations of other health interventions (whether aimed at feasibility, acceptability, safety, effectiveness, outcomes, cost effectiveness of implementability, and regardless of intervention setting or study design), the HRB has a dedicated support scheme for this purpose called "Definitive Trials and Feasibility Awards (DIFA)".
- Applications which are solely literature reviews, stand-alone systematic reviews, audits, surveys, needs assessments or technology development (although these elements may be part of an integrated research study).
- Applications which are solely or predominately developing the infrastructure for biobanking, databases or patient registers without a predominant research element.
- Applications from individuals applying for, holding, or employed under a research grant from the Tobacco industry.
- 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.

4 Funding Available, Duration and Start Date

The HRB aims to support **up to ten awards** in this round at an approximate cost of €3.7M. It is the HRB's expectation that fellows will be working on the award **part-time with a minimum of 0.5 FTE**

and typically a maximum of 0.6 FTE, and that awards will have a duration between 48 and 60 months.

The fellowship will support the part-time salary for the CSF Fellow, and research-related costs up to a maximum of €50K.

- **Salary-related costs** for the pro rata salary-related costs of the Lead Applicant (LA). The HRB funding will cover the corresponding FTE of the salary-related costs of the locum replacement of the LA in line with the appropriate professional scale. Where the LA is based in private clinical practice (e.g., General Practitioner), the salary may directly support the FTE of the LA dedicated to the grant and the academic contract offered should be in line with the Host Institution (HI) clinical academic scale. The HRB will not buy out existing research time.
- **Research-related costs** can be requested up to a maximum value of €50K over the lifetime of the award including
  - Research running costs
  - FAIR data management costs
  - Small equipment costs up to €2,000
  - Dissemination and knowledge exchange costs
  - Training and Development allowance
  - Research Experience Abroad.

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

Note: This is a fellowship award focused on advancing the career development of a named individual. It does not provide funding for other research personnel, including PhD candidates.

Note: In the event that an CSF fellow secures a tenured academic position during the lifetime of the fellowship, payment of the CSF fellow's salary must cease. Requests to repurpose this budget to recruit other personnel or to enhance research-related costs will not be approved by the HRB. However, the HRB may continue to provide the costs of the fellow if they can demonstrate that they can continue the research project and have the support of a research institution.

5 Eligibility Criteria

This call is not open for HIs from Northern Ireland.

5.1 Lead Applicant

The **Lead Applicant (LA)**, i.e., **the prospective fellow**, will serve as the primary point of contact for the HRB during the review process and for the award management and monitoring, if successful. They will be responsible for the scientific and technical direction of the 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.

5.1.1 Lead applicant's suitability

LAs must have a career goal of becoming an independent clinician researcher and a particular ambition to make a difference in policy and practice through their research. They must demonstrate prior research skills, methodologies and scientific knowledge acquired during their PhD and now have a research vision and an ambition to broaden and enhance their research knowledge, skills, methodologies and capabilities, and networks to support their research career goals.

LAs should be able to demonstrate:

- A track record of research contribution to scientific knowledge demonstrated by relevant research outputs as leading author.
- Some experience in communicating research outputs (e.g., conferences, presentation at institutional level, etc.)
- Prior examples or evidence of future potential for developing meaningful partnerships and collaborations with researchers across discipline, with other centres across settings or geographies.
- Experience in, or future vison and potential to support the planning, conduct and translation of research findings into policy and/or practice.
- Ability to show ownership of the research and that they are beginning to shape their own research vision beyond this award.

Please note that the HRB is a signatory of DORA (San Francisco Declaration of Research Assessment) and in line with its principles the HRB explicitly guides reviewers to assess the track record of LAs aligned with DORA principles, as appropriate.[5] [6]

5.1.2 Lead Applicant's Eligibility

LAs can be individuals who are currently:

- Working in Ireland
- Working overseas
- On a career break

A Lead Applicant must:

- Possess a PhD degree or demonstrate equivalent research experience as defined in the 'Towards a European Framework for Research Careers'.[7]

[5] https://www.hrb.ie/funding/funding-schemes/before-you-apply/how-we-assess-applications/declaration-on-research-assessment/

[6] https://sfdora.org/

[7] https://cdn5.euraxess.org/sites/default/files/policy_library/towards_a_european_framework_for_research_careers_final.pdf

  - PhD equivalency is defined as at least four years **full time research experience** post-primary degree. Full-time equivalent research experience is measured from the date when a researcher obtained the degree entitling them to embark on a doctorate (either in the country in which the degree was obtained or in the country in which the researcher is recruited), even if a doctorate was never started or envisaged. Equivalency must be granted before a submission of an application, please contact the HRB to discuss equivalency. The PhD Equivalence request form can be found here.
  - Professional and taught doctorate degrees are not accepted as equivalent to a PhD.
  - For the purpose of this call, the date of a PhD is defined as the year that the degree was successfully defended (not the conferred date).
  - For individuals, who hold more than one PhD degree, the date of the earliest degree will define the LA's eligibility.
- Have completed his/her professional training (Medics need to have completed their general training and may be at Specialist Registrar (SpR) level).
- Apply from a HI based in the Republic of Ireland.
- Hold (or will hold at the time of the award being made):
  - a clinical post in the Irish health service or social care organisation which covers or will cover the duration of the award if successful (e.g., SpR, hospital consultant, nurse practitioner, public health practitioner, physiotherapist)

or

  - a clinical post in a private practice (e.g., General Practitioners, private physiotherapy practice, private dentist practice, private pharmacy)

or

  - a post in a health and social care organisation (e.g., Tusla, Section 38 or Section 39 agencies)

or

  - a joint clinical and academic teaching/education position without a research element within a Higher Education Institution and the Irish Health Services or other social care organisations

or

  - if not currently working in Ireland, have the support of a HRB approved HI and have already obtained or are negotiating a post in a clinical or a social care services organisation in the Republic of Ireland
- Only apply to one HRB postdoctoral fellowship scheme (ARPP 2023 or CSF 2023). Only one application per LA to these two schemes will be considered.

Please note that active research experience will be considered when assessing the LA's eligibility and track record to date, which means career breaks, flexible working arrangements, changes in sector (e.g., industry, health organisation/agency) will be taken into account when assessing research experience.

Applicable to medical doctors only:

- Medical doctors with a hospital consultant post must not provide private practice during the award. The HRB expects applicants who are currently on Type B consultant contracts to negotiate with their hospital group and HSE to provide a work-plan that limits private practice during the award. This should be confirmed in the letter of support from the employer in-practice at the time of the application.
- Medical doctors who currently do not have a hospital consultant post and are trying to obtain one at the time of this application:
  - Must have the endorsement of the Head of Medical School from the HI they will be applying from. The letter on headed paper and signed by the Head of the School must acknowledge the medical school is cognizant of the application to the HRB scheme. If the application is successful, this will facilitate the medical school in association with the hospital group to offer a fixed-term academic consultant post at a level of Senior Lecturer/Associate Professor (depending on the title used in the relevant University). It is currently envisaged the awardee would have between 0.5 and 0.6 FTE protected research time supported by the HRB and 0.4 and 0.5 FTE teaching and clinical time supported by the HEI and relevant hospital group. The split between clinical and teaching time must be negotiated between HEI, HSE and hospital group by the applicant during the application stage and finalised prior to the start of the award.
  - **Only Type A contracts** will be allowed for individuals obtaining new consultant posts.
- Medical doctors applying while conducting their clinical specialty (SpR level) are eligible to apply even if the clinical contract will not cover the full duration of the award. At the time of applying for a new consultant contract during the fellowship they must have the endorsement of the Head of Medical School from the HI, and this must be provided to the HRB. As stated above **Type A contracts only** will be allowed for individuals obtaining new consultant posts.

Lead Applicants must <u>not</u>:

- Be already recognised as independent investigators/principal investigators by
  - Having already received any substantial research grant as lead investigator/lead applicant with a value equal or above €100K, including if the LA was work package leader in funding schemes from the European Commission. LAs are eligible if they were recipients of PhD student scholarships, fellowships, or other individual awards.

and/or

  - Lead an existing research team and be named as the primary supervisor previously for a PhD candidate or other early career researchers.

In either or both instances the LA is not eligible to this fellowship scheme.

Notes: LAs such as medics, nurses and midwives, dentists, pharmacists or any other health and social care professionals, who are currently engaged in research only or research and other academic activities but not involved in patient-facing care <u>are not</u> eligible to apply to this scheme and should

apply to the other HRB postdoctoral scheme 'Applying Research into Policy & Practice' (ARPP) (2023). That particular scheme is part of the research career path dedicated to academic-based researchers. If you are not sure which scheme is more suitable for you to please contact the HRB.

Only one application per LA to this scheme will be considered.

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

5.2 The Research Team

The prospective fellow can propose a research team to support the intent set out in the proposal and this shall comprise of a mentor and up to 10 Collaborators. (There are no co-applicants in HRB fellowship schemes).

The contributions from the research team can span different backgrounds, disciplines, methodologies, professions, settings, sectors, or countries as appropriate to address the research question and training ambitions and to apply the research findings into policy and/or practice.

5.2.1 Mentor

The selection of a mentor, who can demonstrate expertise in applied research, capacity building and coaching, will be crucial for the successful fellows. The LA **must nominate a mentor** to provide support and guidance to the LA during the award for the research project, career milestones and research vision. The mentor will also be supporting the LA in the acquisition of the set of skills necessary for having an effective and active role in actionable knowledge in health research. The Mentor will need to approve their participation and complete the mentor section in the online application before it is submitted.

The mentor should be an individual who has strong evidence of:

- Expertise and a skillset in knowledge application and/or translation and/or implementation
- Experience in networking, collaborating and ideally influencing clinicians, executives, health care personnel, policy makers and/or other relevant stakeholders
- Leadership experience
- Experience in conducting research projects and programmes
- Track record in scholarly publication and communication (peer-review articles, research data publications, national or international briefing/reports, etc.)
- Coaching and mentoring.

5.2.2 Collaborators

An official Collaborator is an individual or an organisation who will have an integral and discrete role in the proposed research and is eligible to request funding from the award when properly justified.

Named collaborators may include investigators or organisations from outside the Republic of Ireland, but an individual or organisation should **only** be named as Collaborator if they are providing specific contributions (either direct or indirect) to the activities. A collaborator may provide training, supply samples or kits, provide access to specific equipment, specialist staff time, staff placements, access to data and/or patients, instruments or protocols, industry know-how, or may act in an advisory capacity. Collaborators can come from a range of backgrounds such as academia, the private sector, a healthcare organisation, the charity sector or a patient group (**up to a maximum of 10 Collaborators can be listed)**.

Note: *It not mandatory to have 10 Collaborators, this is to allow for flexibility should this seem appropriate.*

Profile details **must** be provided for ALL official collaborators. In addition, each official collaborator **must** complete a **Collaboration Agreement Form**. A template Collaborator Agreement form will be made available on GEMS for download.

If access to samples, vulnerable population groups, healthy volunteers or patients, data, databases, or a link to an existing national or international study (e.g., an existing cohort or longitudinal study) are an integral part of the proposed project, evidence of commitment and access must be demonstrated by having the Data Controller or key Gatekeeper of a study included as a Collaborator.

*A '**data controller**' refers to a person, company, or other body that decides how and why a data subject's personal data are processed. If two or more persons or entities decide how and why personal data are processed, they may be 'joint controllers', and they would both share responsibility for the data processing obligations[8]. Otherwise, they should be named as Collaborators unless the exceptions apply (the dataset is publicly accessible or the CSO has given a letter of comfort).*

The LA will be asked to describe any relevant agreements that they have entered into to facilitate their partnership working. The terms of any collaboration should be determined early, and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, ownership and copyright, access and sharing of data and samples etc. when working up Partnership proposals.

6 Training and Professional Development

The CSF fellowships are personal research awards and are more than a means to fund a research project. A combination of the proposed research project and a good training plan in a strong research training and mentorship environment will provide the LA with the most valuable experience during the fellowship.

The training and professional development activities should clearly support the individual to work in the proposed research area and take an active role in applying research findings into policy and practice in local, national and/or international context. Furthermore, the training and professional

[8] https://www.dataprotection.ie/sites/default/files/uploads/2019-07/190710%20Data%20Protection%20Basics.pdf

development should facilitate the LA, if successful, in progressing during the postdoctoral training towards a more independent research level.

6.1 Training and development plan

To that end, applicants are required to provide a detailed personal training and development plan, which has been agreed with their mentor. This plan should include:

- Formal and informal career development training
- Research skills/techniques training specific to the project
- Generic research skills training, such as data handling/protection, good oral and written communication/presentation, IT, and time-and resource-management
- Methodological/experimental design
- Statistics
- Dissemination and knowledge sharing and open resources
- Consideration of intellectual property issues
- GDPR and ethical issues.

Note: *Applications which do not contain a convincing training and development plan are unlikely to be competitive.*

6.2 Travel Grant (Research Experience Abroad)

The HRB recognises the valuable experience that can be gained by researchers who spend time working with research groups abroad. You can avail of the Travel Grant by planning a longer stay abroad (usually maximum of one year) or shorter visits and trips where appropriate and justified. LAs availing of this opportunity must describe their plans, include the details of the Sponsor abroad and the travel-related costs.

A **Letter of Support from the Sponsor abroad** on headed notepaper as evidence of the Sponsor's willingness to allow you to gain experience in his/her Department/Institution is required for the submission of this application.

7 Host Institution

A HRB HI 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 HI status is a requirement to submit an application under all HRB award schemes. The **HI for the award** is normally that of the **LA** 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 HI no later than two calendar months before the closing date of a call. A list of currently approved HRB HIs and information on the

application process for research performing organisations to be approved as HRB HIs can be found on the HRB website[9].

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

A **HI Letters of Support** must be provided at application stage. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*Host Institution - insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognised by the host institution upon receipt of the CSF award as a contract researcher; (ii) has research space/facilities for which he/she is fully responsible for at least the duration of the award. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

It is the responsibility of the LA to ensure that applications are completed in full, and all necessary documentation is received by the HRB on, or before, the closing dates indicated.

8 Application, Review Process and Assessment Criteria

8.1 Grant E-Management System (GEMS)

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie/).

The application must have been reviewed and approved by the signatory approver at the research office (or equivalent) in the HI before it is submitted to the HRB. Therefore, applicants should ensure that they give the signatory approver sufficient time before the scheme closing date to review the application and approve it on GEMS. Please note that many HIs specify internal deadlines for this procedure.

The HRB is committed to an open and competitive process underpinned by international peer review. To ensure the integrity of the assessment process, conflict of interest and confidentiality are applied rigorously in each stage of the process.

8.2 Review Process

Applications will be initially checked for eligibility by HRB staff members. Where an application is deemed to be out of scope, the chair of the international grant selection panel will be consulted to confirm the recommendation.

Following the initial eligibility check, each eligible application submitted to this scheme will undergo a two-phase review process.

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

Phase 1 – International Peer Review, Public Review and Shortlisting

For each eligible application, the HRB aims to receive written feedback from at least three international peer reviewers and two public reviewers.

International peer reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Peer reviewers will focus on the stated assessment criteria for the call and will provide comments as well as a score which is visible to the HRB and to panel members.

Public reviewers will only assess the quality of PPI in the application and will provide comments and an overall rating which will be shared with the panel. Public reviewers will not provide a score.

Public Reviewers are asked to comment on the following:

- The Plain English Summary (Lay Summary)
- Relevance of the Proposed Research Question
- Public and Patient Involvement in development of and throughout the project
- Research Design - inclusion of research participants (where applicable)
- Dissemination and Potential Impact of the Proposed Work

Both peer and public review comments will not include any reference to the reviewer's identity or their submitted scores or rating.

The HRB will share the public review feedback with the PPI Ignite Network team in the HI where applicable.

Applications will be shortlisted for considerations by the Panel using the average of the peer review scores.

Typically, approximately twice as many applications are shortlisted than are expected to be funded by this call.

Applicant response

The LA and research team of shortlisted applications will be provided with a time-limited opportunity to respond to peer and public review comments (see Section 9: Timeframe).

Once notified that the application is short-listed the peer review and public review comments will be made available to the Lead Applicant on their GEMS personal page. The Lead Applicant will have 10 working days only to submit their response through GEMS, and the response **has a maximum word count of 2000 words only** for the peer review response (including references) and **500 words only for the public review response.** No figures can be uploaded at this stage. The Applicant response is a **narrative only** opportunity for the applicant to address the review comments. The response will be provided to members of the Interview Panel, in advance of the Panel meeting, along with the application, the peer and public review comments and rating.

This phase of the assessment process is extremely important, providing an opportunity to address any factual errors, conceptual misunderstandings or differences of opinion that can be perceived as weaknesses or concerns by the Panel. The response should be succinct yet clear. It should address all

significant concerns and/or weaknesses described in the reviewer's feedback point by point. The LA and Research Team may take on board any constructive feedback that may help to improve the application, if funded. If the applicant team disagrees with a reviewer's statement, they should explain why and provide additional information. Responses that could be construed as argumentative should be avoided. Please note HRB reviewers volunteer their own time in reviewing grant applications.

Phase 2 - Interviews with International Panel

All shortlisted LAs will be invited to attend an interview. An international grant selection Panel will be convened to interview shortlisted applicants, and members are assigned as lead and secondary interviewers to specific applications.

Panel members have access to the application, peer and public reviews and the applicants' response. HRB staff members are present at the meeting to clarify any procedural aspects for the Chair or Panel members and to take notes for the feedback process.

The panel will review the strengths and weaknesses of the application relating to the review criteria detailed below. Successful applicants are expected to score well in all review criteria. While PPI is not a stand-alone assessment criterion, it may influence scores under any criterion as relevant to the application.

To prioritise between applications with the same score around the funding cut off in the Panel ranking list, the sub-score awarded to the **LA assessment criterion** will be the **first ranking factor**. Where the Applicant sub-score is also the same the balance between the **health and social care profession** of the LA will be the **second ranking factor** to prioritise applications. This means the under-represented profession within the ranked list will be prioritised. In line with the **HRB Gender Policy**, **the gender balance** of LAs within the ranked list recommended for funding will be the **third ranking factor**.

The recommendations of the Interview Panel will be presented for approval at the next scheduled HRB Board meeting. When the Board of the HRB has approved the process and recommendations, HRB staff will contact the applicants to notify them of the outcome. It is estimated that from the deadline of the call to the HRB decision after the assessment will take approximately seven months.

8.3 Assessment Criteria

The following assessment criteria will be used to assess applications **by peer-reviewers and the interview panel reviewers**. Successful applications will be expected to **rate highly in all criteria**.

1. **The Lead Applicant (40%):**
    - Standing and potential of the LA to progress towards becoming a future independent researcher and potential leader in applied health and social care research
    - Quality and appropriateness of the training and development activities supporting the LA's progression stage.
2. **The Support (30%):**

- Suitability and breadth of the research team and the mentor
- Suitability of the HI and wider support environment.

3. **The Research project (30%):**

- Demonstrated need, relevance and timeliness of the proposed research project and clarity of the route to impact on health and social care policy and/or practice (national and/or international)
- Appropriateness of the research approach and methodologies and feasibility of the project.

The **Public review** does not constitute a standalone scoring criterion in this round; however, it may influence discussions under each assessment criterion as relevant to the project.

8.4 HRB Career track CV

As signatory of the DORA declaration, 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[10]. The HRB is using a narrative-like CV, the HRB Career Track CV, for research career schemes, where the person is at the core. In the CSF the HRB CV is mandatory for **LAs and Mentors**. It aims to allow researchers to craft a convincing rationale and present their career paths in a much more comprehensible way. Such a CV should be tailored to individuals completing it and to the funding opportunity they are applying for.

Please see additional information here.

9 Timeframe

Date	
06 December 2022	Call Opening
02 March 2023 @13:00	Call Closing
March 2023	Eligibility checks
March to early June 2023	Scientific and Public review
Mid-June 2023	Shortlisting of applications
Mid-June 2023	Applicant response opens
Last week of August 2023	Panel Interview Meeting
Late September 2023	HRB Board Decision
October to November 2023	Budget negotiations and contracting
01 November 2023	Earliest start date

10 Contacts

For further information on the CSF 2023 contact:

[10] https://www.hrb.ie/funding/funding-schemes/before-you-apply/how-we-assess-applications/declaration-on-research-assessment/

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The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's policy on ineligibility decisions is available at Appealing ineligibility decisions in funding schemes (hrb.ie).

Appendix I: Detailed Guidance on the Application Form

Only registered users of the GEMS system can apply for grants. In order to submit an online application to the HRB, applicants are required to register at the following address: https://grants.hrb.ie

*Please refer to the **GEMS Technical Guidance Note**[11], available on the left-hand column of your GEMS profile homepage, for further information.*

The LA must create and complete the application, apart from the named mentor completing their section. The Mentor must also approve the content of the application.

LAs can register on GEMS and they will receive an email to confirm their registration and log in details. The LA can then add information on their contact and CV details in 'Manage My Details' section of GEMS.

LAs previously registered on GEMS can login to GEMS and update any information regarding their contact and CV details in 'Manage my details'.

Once logged in to GEMS applicants are taken directly to the Home page which is the starting point to create a new Grant application.

The LA will be asked to complete a check list of mandatory questions. In order to access the application form, the LA must satisfy the conditions of this check list. The checklist is as follows:

Lead Applicant Eligibility	
I have read the Guidance Notes for the CSF 2023 call and reviewed the main changes applied to the CSF 2023.	☑
I am clear about the role of the authorised signatory in the nominated Host Institution, and I am aware that I need to build sufficient time into the application process for the HI to access, review and approve my final application for submission to the HRB through the GEMS system.	☑
I confirm that I am an EU citizen or, if from outside the EU, that I have (or will have at the time of the award) a permanent Irish resident status or a valid work permit.	☑
I confirm that I have a PhD or equivalent, which has been previously approved by the HRB in line with CSF 2023 Guidance (page 8).	☑
I confirm that I have completed my professional training or, if a medic, that I have completed my general training. (Please see pages 8 and 9 of the guidance notes for further information.)	☑
I confirm that I hold or will hold at the time of the award being made (1) a clinical post in the Irish health service and social care organisation, or (2) clinical post in private practice, or (3) a post in a health and social care organisation, or (4) a joint clinical and academic teaching/education position which covers or will cover the duration of the award if successful.	☑
I confirm that I have not been in receipt of any substantial research grant as lead investigator/lead applicant with a value equal or above €100K, including acting as work package leader in funding schemes from the European Commission. (Please note that fellowships and other individual awards such as career development awards are allowed.)	☑
I confirm that I have not yet established a research team nor have supervised/am supervising and mentoring early-stage researchers as primary supervisor.	☑

[11] https://research.ie/assets/uploads/2020/05/CCGT-Grant-Application-System-Technical-Guidance-Notes.pdf

I confirm that I am not applying to ARPP 2023.	☑

Application Scope Eligibility	
I confirm the application falls within the scope of Population Health Research (PHR), Health Services Research (HSR) or Clinical Research as outlined on pages 4 and 5 of the guidance notes.	☑
I confirm the application does not include any item listed under out-of-scope items not funded by this scheme as detailed on page 5 of the guidance notes.	☑

Consent	
By submitting this application, I consent to (a) sharing of my data outside of the European Economic Area (EEA) for the purpose of international peer review, and (b) the use of my data for assessment of my application; monitoring of successful awards; and evaluation of HRB's approach to funding and investment in research, in line with HRB policies and as detailed in the CSF 2023 Call Guidance Notes.	☑

The LA will be then able to start the application. Further details for completing each of the main sections of the application form are provided below.

Host Institution

For the purposes of contracting, payment, and management of the award, HRB funds can only be awarded to HRB approved HIs. Please note that this call is not open for HIs from Northern Ireland. The HI for the award is normally that of the **LA**, but it may be another organisation/institution designated by the research team, where it is clearly justified. In GEMS you will be asked to identify a HI (from this list) and type it in full (do not use acronyms such as UCD, TCD, NUIG). Once you have entered the first 3-4 characters of the HI, you will be assisted with auto-select options. It is important that the HI name is entered accurately and in full as an incorrect entry may result in delays in attaining HI approvals.

If you wish to propose a HI which is not on the HRB list, you are advised to contact the HRB at gemshelp@hrb.ie.

Note: In order to be eligible to apply for funding, an Institution must have been approved as a HRB HI no later than two calendar months before the closing date of a call, only pre-approved HIs will appear in this list.

Signatory Notification (within Host Institution)

Once the **HI** is selected at the initial stages of application creation, this will allow the LA to notify the authorised signatory (Dean of Research or equivalent person authorised to endorse research grant applications for the HI) in that HI of the LA's intention to submit an application to the CSF 2023 scheme. The signatory's details are pre-populated in the system, so the applicant just needs to click 'NOTIFY' within GEMS. We recommend that **you notify the HI signatory** of your intention to apply as

soon as possible in the application process. The signatory will receive an email from GEMS with the name and email details of the LA and if they have any queries or clarifications, they can engage directly to resolve them with the LA. The HI signatory must confirm their willingness to participate as HI for the application through GEMS and once they do this a PDF of the application will be available for them to review with a view to them ultimately approving the final version for submission to the HRB.

1 Project Details

1.1 Project Title

You are asked to provide a title that clearly describes the research to which this application is related. This should be descriptive and concise and should reflect the aim of the project. There is a **200 characters** maximum limit.

1.2 Project Duration and Start Date

Please indicate the expected length of the proposed project in months (minimum duration of 48 months and maximum duration is 60 months for part-time) and the proposed start date. The earliest start date is 01 November 2023.

1.3 Current type of contract and part time arrangements

Please detail the type of contract you currently hold (e.g., clinical, joint clinical and academic, clinical post in a private practice, post in a health and social care organisation etc). For medical doctors the type of contract should also be highlighted (e.g., Type A). The word limit is **30 words.**

Do you have research protected time in your current role/contract?

If **Yes,** state the full time equivalent (FTE) of research time currently protected.

Please note you must have between **0.5 FTE and 0.6 FTE** for the fellowship.

Clearly specify and explain:

- The nature of the time you wish to buy out during the fellowship (e.g. clinical including private practice, academic but not research, etc). Please note the HRB will not buy out any protected research time you have in your current contract.
- How you will fulfil the main objectives of the fellowship with the proposed part-time arrangement, integrated with clinical practice. Please note that block periods dedicated to research are not allowed.

The word limit is **300 words**.

Letters of support:

1. **Letter of support from current employer in-practice:** LAs must provide a letter of support on headed paper from the clinical or social care organisation where they are or will be providing care and are currently or will be employed. The letter signed by CEO/Department Manager/or other relevant person must state the support for the research protected time and part-time arrangement proposed within this application. For medical doctors with type B consultant contracts the letter should also confirm that the LA will limit the private practice during the award, if successful.
2. **Letter of support from the HI:** LAs must provide a formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital which must include the following information; [Host Institution - insert name] which is the host institution of [applicant - insert name] confirms that [applicant - insert name]: (i) holds an employment contract which extends until [insert date] or will be recognised by the host institution upon receipt of the CSF award as a contract researcher; (ii) has research space/facilities for which he/she is fully responsible for at least the duration of the award. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.
3. **If applicable, letter of endorsement for medical doctors:** medical doctors who currently do not have a **hospital consultant** post and are trying to obtain one at the time of this application or by the time they will start the fellowship must provide a letter of endorsement from the Head of Medical School at the HI, they will be applying from. The letter on headed paper and signed by the Head of the School must acknowledge that the medical school is cognizant of the application to the HRB. In addition, the School will provide support in facilitating the offer of a fixed-term academic consultant post at a level of Senior Lecturer/Associate Professor (depending on the title used in the relevant University) in association with the hospital group. Please note that **only Type A contracts** will be allowed for individuals obtaining new consultant posts

1.4 Project Lay Summary

This lay summary is similar to the Project Abstract in that you are asked to describe what you propose to do, why you think it is important and how you are going to go about conducting, analysing and drawing conclusions from the research. The difference is that it needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience. It should not be copied and pasted from elsewhere in the application. The lay summary may be used when providing information to the public with regards to the variety of research funded by the HRB and may be posted on the HRB website. A well-written lay summary will enable peer reviewers and Panel members to have a better understanding of your research application. The word limit is **300 words.**

1.5 Project Abstract

This should be a succinct summary of the proposed research. This structured summary should clearly outline the background to the research, the aims, and hypotheses of the project. The objectives of the project and what the work is expected to establish should be described. It provides a clear

synopsis of your application and should set the research application in context. The word limit is **300 words**.

1.6 Keywords

Please enter up to **5 keywords** that specifically describe your research project.

2 Personal Declaration

Please provide a personal declaration which reflects your research and career goals, why you are well suited for the CSF Fellowship, and how this award will contribute to their attainment. The word limit is **200 words**.

3 Lead Applicant's Details

3.1 GEMS Profile Details – Basic CV information

The **LA**'s CV details (Name, ORCID, Institution, profession, education and employment history) are managed under the "Manage my Details" section of your GEMS account.

ORCID: The HRB is now an ORCID member. All researchers associated with an application are encouraged to include an ORCID iD by updating their GEMS profile under 'Manage my Details' and this will feed automatically into the application form. The ORCID profile should be up-to-date and can include all information found in a traditional CV, including your publication list, history of organisational affiliations, and other relevant information about your academic track record.

You have also the option to import your publication record from ORCID profile in addition to PubMed. Please note this is not a mandatory field for submitting your application. For more information and to register please see https://orcid.org/.

Please note that you **do not** need to complete or update your publications or funding record under 'Manage my Details' as they will not feed through to this application and you will be asked to enter them manually in the section below.

Gender

Please select:

- Man
- Woman
- Other gender identity
- Prefer to not disclose

This question is included with the application form in light of the **HRB Gender Policy**. The HRB has the responsibility to support everyone to realise their full potential in order to ensure equality of

opportunity and to maximise the quantity and the quality of research. The information will not be shared with reviewers, and it is for HRB internal use only.

3.2 Type of Researcher

Please describe yourself as:

- Health and Social Care Practitioner with a joint faculty position
- Health and Social Care Practitioner

3.3 Breaks from research

Please reference any breaks from research. The word limit is **150 words.**

Note: In this section you may want to mention breaks from research, such as statutory leave, secondments, flexible work arrangements or other relevant changes (e.g., sector or discipline) that may have affected or influenced your progression as researcher. These periods will be taken into account to assess the overall active research experience for eligibility and assessment purposes. Please state the period and the reason.

3.4 Key contributions

The aim of this section of the CV is to highlight key contributions that provide relevant context for reviewers and panel members. There are four different categories of contributions, and you should aim to cover as many as possible.

The activities under each category will be assessed in the context of your career stage and against the objectives of the scheme.

3.4.1 Contribution to the generation of knowledge

This section focuses on how you have contributed to the generation of knowledge, new ideas and hypotheses, and tools. This encompasses how you have communicated your ideas and research results (written and verbally), as well as funding and awards that you have received.

- List up to five research outputs that are most relevant to this application and include one reference per output, if applicable. For each output provide a short outline, your specific role, the significance and influence to the research field and/or discipline and/or to health policy and/or clinical practice and resulting impact, if any. The word limit is **400 words**.
- Provide a short statement of your overall contribution to the research field and/or discipline and/or policy and/or practice. The limit is **100 words**.
- Reference up to five independently peer-reviewed research funding awards (including those received from the HRB) most relevant to this application and please specify your role on each: Principal Investigator, Co-Principal Investigator (Co-Lead), Co-Applicant or Collaborator.

Research outputs: They can include datasets, software, publications, commercial or entrepreneurial or industrial products, educational products, clinical practice developments, policy publications, and other similar items. If an output has a DOI please only include this. Research outputs should be examples of rigorous science following high standards, that are reproducible, and others can build upon. Please indicate to what extent these outputs have been made openly available (providing evidence) to the research community and to potential users of research outputs.

Metrics: Please **do not** include information related to H-indexes, impact factors, or any type of metric that refers to the journal, publisher, or publication platform. The scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published. If you wish to reference publication citations, please note they should only be used to complement the narrative component of the CV and not in isolation.

3.4.2 Contribution to training and development of others

This section highlights your expertise which was critical to the success of other individuals either within your team, other teams and supervision and mentoring.

Please include some examples such as team support, supervision and/or mentoring activities, teaching activities, workshops or summer schools' involvement or support you provided to the advancement of colleagues (junior or senior) or strategic leadership by directing a team. The word limit is **200 words.**

Note: the primary supervision of research staff funded through an award secured in your name as LA will render you ineligible for CSF 2023.

3.4.3 Contribution to wider research community

This section emphasises the engagement to progressing the local and international research community.

This may include:

1. Commitments including editing, reviewing, refereeing, committee/panel work and your contribution to the evaluation of researchers and research projects
2. Contributions to increasing research integrity, and improving research culture (equality, diversity, mobility of researchers, and reward/recognition of researchers' broad range of activities, open science initiatives)
3. Appointments to positions of responsibility such as committee membership and corporate roles within your department, institution or organisation, and recognition by invitation within your sector
4. Establishment of local/national/international collaborations, partnerships and networks (including interdisciplinary and cross settings)
5. Strategic leadership by directing an organisation, company, or institution. Please note, this list is not exhaustive.

Please provide some examples in bullet points under selected headings as most relevant to your career and experience to date. The word limit is **200 words**.

3.4.4 Contribution to broader society

This section emphasises societal engagement and knowledge exchange.

It may include:

1. Working with policymakers and knowledge users
2. Public, patient and carer involvement in research (PPI), and collaborating with particular societal
3. Science outreach activities for the general public or subsection of the general public
4. Engagement with industry and the private sector.

Please note, this list is not exhaustive.

Please provide some examples in bullet points under selected headings as most relevant to your career and experience to date. The word limit is **200 words**.

4 Project Description

Please ensure that your application is focused, and that sufficient evidence is provided to enable the international peer reviewers and grant selection panel members to reach a considered judgement as to the quality of your research application, its potential health impact, and its feasibility.

The Project Description must include:

4.1. Research Question

4.2. Current Knowledge, Background to the Area, Relevance and Knowledge Gap

4.3. Overall Aim

4.4. Objectives and Deliverables

4.5. Research Design and Methodological Approach

4.6. Impact Statement

4.7. IP Considerations

4.8. Dissemination and Knowledge Exchange Plan

4.9. Project Management

4.10. FAIR Data Management and Stewardship

4.11. Public, Patient and Carer Involvement (PPI) in the Research Project

4.12. Gender and/or Sex Issues in the Research Project

4.13. Potential Safety Risks and Ethical Concerns

4.14. Biobanking

4.15. Project Description Figures

4.16. References

4.1 Research Question

Clearly state the research question behind the proposed work. The word limit is **50 words.**

4.2 Current Knowledge, Background to the Area, Relevance and Knowledge Gap

Describe the background to the research application and detail the size and nature of the issue to be addressed. **We expect that evidence supporting the case for the project has been gathered systematically**, i.e., as systematic reviews or other evidence synthesis formats. Simple literature overviews are not sufficient. Evidence synthesised systematically should include evidence of (1) a systematic identification of previous work, (2) critical appraisal, (3) synthesis of the evidence and (4) interpretation of findings. Where available, include a description of any pilot work, professional and consumer consensus studies already undertaken.

Please reference any documented need for this area of research, including information on burden on health or the healthcare system. Have any potential users of research outputs been involved in identifying the research question (e.g., patients, healthcare professionals, policymakers)? Explain why this research is both important and timely. Show how your research will add to the knowledge base/advance the state of the art in this area. Be aware that the peer reviewers reading your application are based outside of Ireland, so it is important to describe the healthcare delivery context in Ireland when discussing issues around need (including specific needs of any under-represented groups), relevance, timeliness, and feasibility. The word limit is **1200 words**.

NOTE: you are strongly advised to read the Guidance Notes and in particular the assessment criteria when writing this section.

4.3 Overall Aim

Please state the overall aim of the research project. The word limit is **100 words.**

4.4 Objectives and Deliverables

Please add a minimum of 3 research objectives. Objectives should be SMART (**S**pecific, **M**easurable, **A**chievable, **R**ealistic and **T**ime-bound). For each objective, list a subset of deliverables which will be used to monitor progress throughout the lifetime of the award if successful. Objectives/deliverables should be mapped against estimated completion timelines in a Gantt chart, and any milestones highlighted.

The word limit is **60 words for each objective and 150 words for the deliverables**.

You must upload a Gantt chart which lists the above objectives and deliverables against the estimated timelines for completion, together with any additional milestones/key dates (e.g., PhD submission). Please note that the preparation and submission of Data Management Plans should also be added as deliverables/milestones of the Programme.

4.5 Research Design and Methodological Approach

Summarise the proposed research plan, providing descriptions of individual work packages and describe how they integrate to form a coherent research application.

Include details of the general experimental approaches, study designs and techniques that will be used. Include details on all stages of the study design including rationale for sampling strategy, justification of sample size and power calculation, details on the design chosen, the methods of data collection, measures, instruments, and techniques of analysis for quantitative and qualitative designs, outcomes measures and plans for data analysis/data management.

Where research involves human participants, please describe the selection criteria and rationale for participant selection considering the relevant population for the issue under study. Are under-served populations/groups considered?

Please justify any exclusions based on age or sex/gender of participants.

Show how your research design will allow you to answer your research question.

The word limit is **4500 words**.

Notes:

You are strongly advised to seek advice and input from an experienced **research design and statistics** expert in advance of submitting your application. **Discrepancies and incorrect approaches in this section represent the most common source of feedback in unsuccessful HRB applications.**

Power calculations and sample sizes must be described and justified, and aligned with the study aim, objectives and goals and the context of the study.

Explain in detail how new techniques and/or or high-risk studies will be managed and suggest alternative approaches should these fail.

Where new methods are being developed, arrangements for establishing validity and reliability should be described. Examples of non-standard questionnaires, tests, etc. should accompany the application or their content be clearly indicated.

Useful links and resources are summarised in Appendix IV.

Has an iteration of the proposed research been submitted to any HRB award scheme in the last 3 years? Yes/No

(If yes)

Award Scheme:

Year of previous submission:

Please briefly describe the changes that have been made to the application. Have the recommendations from the previous peer, panel, or public review you received influenced the changes you have made? The word limit is **300 words**.

4.6 Impact Statement

Please describe the likely potential of the research findings from this project to be applied into policy and practice – at local and/or national and/or international context – and the pathway to achieve this. Outline the activities, skills and engagement with key stakeholders, you will need for this proposal. Describe the potential benefits and the resources that will make the plan feasible, and the anticipated timescale for any proposed benefits to be realised over the short, medium, and long term.

This statement should be specific and provide information that the external reviewers will find helpful in assessing the potential impact of the proposed research. Impact statements should be written primarily in plain English. The word limit is **400 words**.

4.7 IP considerations

The LA together with the HI has a duty to the public to ensure that discoveries and advancements in knowledge arising from any award are translated for public benefit including but not limited to commercial development of new therapies, diagnostics, materials, methodologies, and software for health[12]. Please consult with the relevant Technology Transfer Office for advice on this section, where appropriate.

Please describe any current Intellectual property (IP) that will be relevant for the study and whether such IP assets are held by the applicants, and/or others outside the research team. Such IP might include software, checklists, scales, protocols, guidelines, questionnaires, or medicinal products for example. Has relevant background IP for your study been identified? If IP is required, is there freedom to operate, such that this research can eventually be translated? What arrangements are in place to manage IP during the study, and ensure it is protected (if appropriate) prior to dissemination? Do you foresee any barriers to use of IP in order for the research outputs to be adopted? The word limit is **300 words**.

4.8 Dissemination and Knowledge Exchange Plan

Include a clear dissemination and knowledge exchange plan to indicate how the research outputs you anticipate producing during and after your project will be disseminated and shared and made openly accessible, in line with HRB Open Access Policy[13]. Research outputs include peer-reviewed

[12] National Intellectual Property Protocol, 'Inspiring Partnership- the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland'

[13] https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/open-access/

publications, non-peer reviewed publications and conference proceedings, reports, policy briefings, guidelines, training materials and so on. Protection of Intellectual Property should be considered before data are disseminated[14].

Applicants are advised to consider the following:

1. The HRB has a mandatory Open Access publication policy; demonstrate how you plan to make all publications open access.
2. Who are the various audiences and communities that need to be targeted if these results are to have any impact? What is your dissemination plan to address this, how will these audiences be reached?
3. Describe any plans for technology transfer.
4. Describe how the findings of this research will be publicised to the HSE or international health community/organisations in a manner that will optimise impact on health policy and/or practice.
5. Please reference aspects of the project/study undertaken to maximise chances of adoption beyond the term of the award.

Types of publication routes include[15]:

- **Green Route:** publishing in a traditional subscription journal. Articles are 'self-archived' (added) to a repository (institutional or external subject-based) and usually made available after an embargo period, which is set by the publisher.
- **Gold Route:** publishing in an open access or hybrid journal. Articles' processing charges (APCs) are-required so that the article is openly available immediately on publication and can be added to a repository (institutional or external subject-based).
- **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/).

NOTE: applicants are strongly advised to read the Guidance Notes and in particular the assessment criteria that will be used to assess applications. The word limit is **500 words**.

4.9 Project Management

Please describe how the research project will be managed. The role of each applicant team member and research personnel member should be clearly outlined. Describe any oversight, advisory or governance structures that are crucial to delivery of the project, including a steering committee or data safety and monitoring committee if applicable. Outline the processes that will be put in place to ensure that the project is well managed, commenting on project management, meetings schedules,

[14] All HRB Host Institutions must subscribe to the National Intellectual Property Protocol, *'Inspiring Partnership- the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland'*, prepared by Government/Knowledge Transfer Ireland to ensure transparent and consistent procedures for managing Intellectual Property from publicly funded research.

[15] https://www.jisc.ac.uk/guides/an-introduction-to-open-access

financial management etc. Describe contingency plans, including how you intend to manage any risks to the delivery of the project. The word limit is **600 words**.

4.10 FAIR Data Management and Stewardship

Describe the general approach to data management and stewardship that will be taken during and after the projects, including who will be responsible for data management and data stewardship. With the support of data stewards or other data-related services support in the institution (typically library and ICT and digital service, etc), all Applicants should address as much as possible the following points below regarding the management of the research data to be generated and/or re-used during the research project.

Please consider the FAIR Guiding Principles for scientific data management and stewardship: **F**indability, **A**ccessibility, **I**nteroperability, and **R**eusability[16].

1. **Data description and collection or reuse of existing data**: (a) What is the type, format and volume of data? (b) How will the data be collected, created or reused?
2. **Documentation and data quality**: (a) What metadata and documentation will accompany the data? (b) Will you make sure globally resolvable unique, persistent identifiers are in use (e.g DOI)? (c) What data quality control measure do you use?
3. **Storage and backup**: (a) How will data be stored and backed up during the research? (b) How will you take care of data security and personal data protection?
4. **Ethical and legal compliance, codes of conduct**: (a) If personal data are involved, how will you manage compliance with legislation on personal data and security? (b) How will you manage legal issues, such as IPR, copyright, and ownership? Which legislations are applicable? (c) Which ethical issues and codes of conduct are there and how are they taken into account?
5. **Data sharing and long-term preservation:** (a) How and when will you share the data? (b) How do you select data for preservation and where will data be preserved long term (e.g. data repository, archive)? (c) What methods or software tools are needed to access data? (d) How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?
6. **Data management responsibilities and resources:** (a) Who (for example role, position, and institution) will be responsible for data management (i.e., the data steward)? (b) What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR?

The word limit is **500 words**.

16 Wilkinson, M. D. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci. Data 3:160018 doi: 10.1038/sdata.2016.18 (2016).

4.11 Public, Patient and Carer Involvement (PPI) in the Research Project

The HRB recognises that the nature and extent of meaningful public involvement is likely to vary depending on the context of each study. Please note PPI does ***not*** *include the recruitment of study participants in research projects. It also does* ***not*** *include work aimed at raising awareness of the public around research, such as media publications of research findings, and outreach activities such as open days in* research facilities.

Useful resources including practical examples of involving members of the public in your research can be found in Appendix IV. Please be aware there are PPI Ignite Network offices in some HIs.

Are you including PPI in your application?

If Yes

Please describe all PPI at each stage of the research cycle:

- Identifying and prioritising the research question
- Design
- Conduct
- Analysis
- Oversight
- Dissemination

For each stage, please include the purpose of this involvement and where applicable how PPI has influenced/changed what work has been planned.

This section should be a succinct summary of public involvement activities. Provide information on the individuals/groups and the ways in which they will be involved. PPI contributors should be representative of the relevant people and communities impacted by the research topic. **Where members of the public, patients or carers are involved, they should be compensated for their time and contributions; this should be reflected in the project budget.**

Please ensure to provide more detail in other sections of the proposal as appropriate.

Important: The PPI section needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience.

If No

Please explain why PPI is not relevant to your project. The word limit is **600 words**.

4.12 Gender and/or Sex Issues in the Research Project

A key objective of the HRB is to strive for gender balance in Irish health research. We encourage a balanced participation of genders in all research activities.

Please note this section is intended to focus researchers on the **research content**, and **not** the gender balance within the research team.

Please identify and explain how you address sex and/or gender issues for this project.

Are there potential sex (biological) considerations for this research?

Are there potential gender (socio-cultural) considerations for this research?

If so, outline how sex and/or gender analysis will be integrated in the design, implementation, evaluation, interpretation, and dissemination of the results of the research application.

If not, you must clearly demonstrate why it is not relevant to the research application; have you done a literature search to confirm this?

Please see Appendix IV for resources on gender and sex considerations in research applications.

The word limit is **400 words.**

4.13 Potential Safety Risks and Ethical Concerns

Please address any potential risk and/or harm to patients or human subjects/participants in the research, if relevant. Please highlight any potential ethical concerns during this study and/or at follow-up stage. Describe any potential ethical concerns that may arise as a result of this research, even if not part of this application, and how you propose to deal with them. If the proposed research includes vulnerable groups, what additional considerations are there for these participants? The word limit is **400 words**.

4.14 Biobanking

Does your application include an element of biobanking? Y/N

If yes, please describe how biobanking within this project will be in compliance with international best-practice ethical considerations and the General Data Protection Regulation, in particular in relation to consent.

You must submit a completed **Infrastructure Agreement** form with details of the biobank. Please describe how you will ensure good practice for biobanking components in this project, with particular regard to quality of sample collection, processing, annotation and storage. Please reference relevant guidelines/standards you will use. Where material will be obtained or stored for a future research purpose, or where you will use material previously obtained for another purpose, please refer to the latest Recommendation of the Council of Europe[17]. Some useful links are in Appendix IV. The word limit is **400 words**.

4.15 Project Description Figures

A file upload option is available to include an attachment to support your Project Description**.** A **maximum of 5 figures**, which can be a combination of images, graphs, tables, scales, instruments, or surveys, may be uploaded as a single document on HRB GEMS. Additional references should not be

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

included here. They must not be embedded within the text of the Project Description. The maximum size is **2MB**. Files should be doc, docx, or pdf.

4.16 References

A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of **30 publications**. Please enter references in the same format.

For publications:

Gallagher PA, Shoemaker JA, Wei X, Brockhoff-Schwegel CA, Creed JT. Extraction and detection of arsenicals in seaweed via accelerated solvent extraction with ion chromatographic separation and ICP-MS detection. Fresenius J Anal. Chem. 2001 Jan 1;369(1):71-80. PMID: 11210234.

For book and printed source citations:

Farrell M, Gerada C and Marsden J (2000) *External review of drug services for the Eastern Health Board*. London: National Addiction Centre.

For data citation[18]:

Authors, year, article title, journal, publisher, DOI

Author(s), year, dataset title, data repository or archive, version, global persistence identifier

5 Details of Research Team

5.1 Collaborative and cross-disciplinary approach

Describe why you have selected the research team members, the overall complementarity of skills, expertise, and disciplines within the team, and how they will converge and work together during the award. Address also any international collaboration and/or collaborations across settings, if relevant. The word limit is **400 words**.

5.2 Mentor

The LA can add a Mentor to an application by entering the name on GEMS. The mentor should be chosen based on their research expertise and ability to guide the applicant in various areas of the research programme.

If the individual is already registered on GEMS, the system will find them and will allow the LA to select her/him. Alternatively, the Mentor can be added manually by entering their name and email details. GEMS will send them an email with login details for completing the registration process and will inform them that they have been invited by the LA to participate in the application as Mentor. Registered Mentor can decide whether to accept or reject their participation. If the proposed mentor rejects participation in an application, the LA is informed and may revise the application accordingly.

[18] https://www.force11.org/group/joint-declaration-data-citation-principles-final

The Mentor who accepts will be able to complete some section of the application and also edit the application. The system will flag if another user is working on the application form at the same time via a pop-up warning. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data, but it is advisable that they contact the other person directly to avoid losing data when applying the override function.

Prior to validation and submitting the application to the authorised signatory of the nominated HI for the final approval stage, the Mentor must also approve the content of the application.

Please note the section below must be complete by the Mentor.

GEMS Profile Details – Basic CV information

The Mentor's CV details (name, ORCID iD, institution, profession, education and employment history) are managed under the "Manage my Details" section of your GEMS account.

Note: The HRB is now an ORCID member. Mentors are encouraged to include an ORCID iD by updating their GEMS profile under 'Manage my Details' and this will feed automatically into the application form. You have also the option to import your publication record from ORCID iD in addition to PubMed. Please note this is not a mandatory field for submitting the application. For more information and to register please see https://orcid.org/.

Please note you do not need to complete or update your publications or funding record under 'Manage my Details' as they will not feed through to this application and you will be asked to enter them manually in the section below.

Gender

Please select:

- Man
- Woman
- Other gender identity
- Prefer to not disclose

This question is included with the application form in light of the HRB Gender Policy[19]. The HRB has the responsibility to support everyone to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. **The information will not be shared with reviewers, and it is for HRB internal use only.**

[19] https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/gender-in-research-funding/

5.3 Mentor Details

5.3.1 Type of Researcher

Please describe yourself as:

- Researcher - Academic
- Researcher - Health and Social Care Practitioner (with a joint academic appointment)

5.3.2 Breaks from research

In this section you may want to mention breaks from research, such as statutory leave, secondments, flexible work arrangements or other relevant changes (e.g., sector or discipline) that may have affected or influenced your progression as researcher. These periods will be taken into account to assess the overall active research experience for eligibility and assessment purposes. Please state the period and the reason. The word limit is **150 words**.

5.3.3 Key Contributions

The aim of this section of the CV is to highlight key contributions of the mentor that provide relevant context for reviewers and panel members. There are four different categories of contributions, and you should aim to cover multiple areas described below and avoid listing and describing solely items from your publication record.

5.3.3.1 Contribution to the generation of knowledge

This section focuses on how you have contributed to the generation of knowledge, new ideas and hypotheses, and tools. This encompasses how you have communicated your ideas and research results (written and verbally), as well as funding and awards that you have received.

- List up to five research outputs that are most relevant to this application and include one reference per output, if applicable. For each output provide a short outline of the stated output, your specific role, the significance and influence to the research field and/or discipline and/or to health policy and/or clinical practice and resulting impact, if any. The word limit is **400 words**.
- Provide a short statement of your overall contribution to the research field and/or discipline and/or policy and/or practice. The limit is **100 words**.
- Reference up to five independently peer-reviewed research funding awards (including those received from the HRB) most relevant to this application and please specify your role on each: Principal Investigator, Co-Principal Investigator (Co-Lead), Co-Applicant or Collaborator.

Research outputs: They can include datasets, software, publications, commercial or entrepreneurial or industrial products, educational products, clinical practice developments, policy publications, and other similar items. If an output has a DOI please only include this. Research outputs should be examples of rigorous science following high standards, that are reproducible, and others can build upon. Please indicate to what extent these outputs have been made openly available (providing evidence) to the research community and to potential users of research outputs.

Metrics: Please **do not** include information related to H-indexes, impact factors, or any type of metric that refers to the journal, publisher, or publication platform. The scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published. If you wish to reference publication citations, please note they should only be used to complement the narrative component of the CV and not in isolation.

5.3.3.2 Contribution to training and development of others

This section highlights your expertise which was critical to the success of other individuals either within your team, other teams and supervision and mentoring.

Please include some examples such as team support, supervision and/or mentoring activities, teaching activities, workshops or summer schools' involvement or support you provided to the advancement of colleagues (junior or senior) or strategic leadership by directing a team. The word limit is **200 words.**

5.3.3.3 Contribution to wider research community

This section emphasises the engagement to progressing the local and international research community.

This may include:

1. Commitments including editing, reviewing, refereeing, committee/panel work and your contribution to the evaluation of researchers and research projects
2. Contributions to increasing research integrity, and improving research culture (gender equality, diversity, mobility of researchers, and reward/recognition of researchers' broad range of activities, open science initiatives)
3. Appointments to positions of responsibility such as committee membership and corporate roles within your department, institution or organisation, and recognition by invitation within your sector
4. Establishment of local/national/international collaborations, partnerships and networks (including interdisciplinary and cross settings)
5. Strategic leadership by directing an organisation, company, or institution.

Please provide some examples in bullet points under selected headings as most relevant to your career and experience to date. The word limit is **200 words**.

5.3.3.4 Contribution to broader society

This section emphasises societal engagement and knowledge exchange.

It may include:

1. Working with policymakers and knowledge users
2. Public, patient and carer involvement in research (PPI), and collaborating with particular societal

3. Science outreach activities for the general public or subsection of the general public
4. Engagement with industry and the private sector.

Please note, this list is not exhaustive.

Please provide some examples in bullet points under selected headings as most relevant to your career and experience to date. The word limit is **200 words**.

Please note section 5.4 and 5.5 must be completed by the Lead Applicant.

5.4 Mentorship arrangements

Please justify your choice of Mentor and explain how this mentorship will be of benefit to your career and the award. Please describe the arrangement you will have in place with your mentor during the award. The word limit is **200 words**.

5.5 Collaborator's Details

The LA can add up to 10 collaborators per application. Unlike the LA and Mentor, the information for Collaborators is not automatically drawn from the 'Manage my Details' section of GEMS but must be entered by the LA. The LA must enter **contact and CV details** for all Collaborators including name, contact information, institution or organisation, present position, employment history, profession and membership details of professional bodies, **Publications and Funding Record** (if applicable) (five most relevant publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) relevant to this application where the Collaborator has acted as Principal Investigator or Co-Applicant).

In addition, for each Collaborator a signed **Collaboration Agreement Form** must be provided. A template Collaboration Agreement Form is available for downloaded from GEMS. Forms must be completed, signed, dated, and uploaded where indicated on HRB GEMS. Please label each form with the name of the relevant Collaborator. Electronic signatures are acceptable on letters/forms that are uploaded on GEMS.

5.5.1 Collaborator's Role

Please detail each collaborator's role during the fellowship and the percentage or proportion of full time equivalent (FTE). The word limit is **100 words**

6 Research & Professional Development Plan

6.1 Overview of the plan

Provide **an overview** of the research and professional development plan and activities you wish to undertake to support your research and professional development during the fellowship. These activities should clearly support you to work in the proposed research area and to take an active role in applying research findings into policy and practice in local, national and/or international context.

The plan may include any specialist skills that may be required to undertake the proposed research project, specific methodological training, or other transferable skills such as management skills; communication or dissemination skills (e.g., conference/workshop attendance; teaching/supervision experience and writing for publication). It is also strongly recommended that you discuss the proposed training plan with your mentor. The word limit is **300 words.**

Note: *Because this is a fellowship it is suitable for applications from mid-stage researchers of strong potential in their research careers and aims to provide a customised research training programme in an environment reflecting their individual talents and training needs, we strongly advise you to think carefully about the research and career development skills necessary to successfully conduct you research project and progress and advance your research career.*

6.2 Research and Professional Development Gantt Chart

In addition to the information provided in this section you must summarise this plan in a **Gantt chart** (or alternative) and upload it to the HRB GEMS system. The Gantt should indicate how the proposed training plan is linked with key milestones and deliverables. Please label this document clearly as the "Research and Professional Development Plan" and upload it to the appropriate section in the GEMS system.

Note*: You are required to provide detailed costs of the training and development activities in the project budget section so these should not be included here.*

6.3 Travel Grant (Research Experience Abroad)

The Health Research Board recognises the valuable experience that can be gained by researchers who spend time working with research groups abroad. In order to avail of this opportunity, you must include it in the application now, as requests for travel-related costs to gain research experience abroad during the course of the fellowship will not be considered. You can avail of the Travel Grant by planning a longer stay abroad (usually maximum of one year) or shorter visits and trips where appropriate and justified.

6.3.1 Travel Grant: Sponsor Contact Details

Please provide the following details for the Sponsor Abroad Name, position, Profession, Institution, and email.

6.3.2 Travel Grant: Overall Plan

Describe where and when you are planning to avail of the Travel Grant, and provide details of to whom you will travel. Please include details of their research programme, how it fits with your research project and training objectives, the proposed timelines, the nature of the research training to be gained, and how this will add value to your fellowship and your future development as a researcher. The word limit is **400 words**.

A **Letter of Support from the Sponsor Abroad** on headed notepaper as evidence of the Sponsor's willingness to allow you to gain experience in their Department/Institution is required for the submission of this application.

Note: *You **must** provide detailed costs associated with this travel grant in the project budget section entered via the HRB online system GEMS.*

7 Infrastructure and Support

7.1 Host Institution Infrastructure and Support

Describe the infrastructure, facilities, specialist expertise and other support available at the HI and/or at other sites where the research will be conducted. Please include details of critical supports in areas such as statistics, research methods, biobanking expertise or regulatory expertise where this is being provided above and beyond the activities/expertise of members of the research team. The word limit is **400 words**.

7.2 Access to 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 unit (e.g., Centre for Applied Medical Imaging, CAMI, Centre for Support and Training in Analysis and Research (CSTAR)) or a biobank are required to provide additional information detailing the scope and nature of the engagement (this include national facilities and/or international facilities and units/networks where justified) at research design or implementation stages. The following information must be provided:

- Name and address of the facility/centre/network.
- Information on the nature and stage/s of the input/advice/collaboration/service.
- Rationale for the choice of facility/centre/network.
- How the proposed involvement enables the planned research to be undertaken to the required quality or timescale.

The word limit is **400 words**.

Applications involving patients which do not detail such input, advice and/or support (and where this expertise is not clearly evident within the applicant team) **must provide a detailed justification** as to why they have chosen not to access such support.

An **Infrastructure Agreement Form** must be completed and can be downloaded from GEMS. The Form must be completed, signed, dated, and uploaded on GEMS. Electronic signatures are acceptable for letters/forms that are uploaded on GEMS.

8 Project Budget

Please provide a summary and justification of the costs and duration associated with the project.

A **full detailed breakdown** of **costings** and **justification for all funding** is required for items listed under each subheading within GEMS.

Note: You are strongly advised to seek guidance from the research office/finance office in the HI before completing this section of the form. The HRB will not provide additional funding in the case of either under-estimates or over expenditure**.**

The total funding available for research related costs will be €50,000 in addition to part-time salaries over 48-60 months. Allowable costs include:

1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	**Lead Applicant (LA):** The HRB funding will cover 0.5 or 0.6 FTE of the salary-related costs of the locum replacement of the LA in line with the appropriate professional scale or of the LA, where the LA is from private practice. Health and social care practitioners must use the salary scale **most appropriate to their professional background** at the most appropriate level and point as relevant to their role and experience in the research, e.g., the consolidated HSE scale, INMO scale, the relevant scale from the social care organisation where working or the most appropriate institutional academic scale (e.g., individuals from primary care). The LA is also required to specify if funding will cover their or the locum salary under the justifications. **Applicants must include annual pay increments (pension contribution, employer's PRSI contribution) in the budget.** Please apply a salary contingency of 3% from 1st October 2024 onwards and note this contingency should be applied cumulatively year on year. The contingency in salaries should be added only where the relevant health and social care professional scale does not include such salary contingencies.
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). If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs etc. Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, Clinical Research Facilities support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form'.

	Costs associated with compensating PPI contributors involved in your research e.g., consultation workshops, time spent reviewing material, costs of participation in advisory groups, travel expenses, payments for time (in line with your Host institutions policies), etc. should be charged to running costs.
3. Equipment	Funding for suitably justified equipment can be included in this section, **at a maximum of €2,000.** 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, and should not exceed €1,200. All costs must be inclusive of VAT, where applicable.
4. Training	Costs associated with training and development in order to acquire specific technical skills and/or professional skills such as leadership, management, etc.
5. Dissemination Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[20]. Please list dissemination costs under the following categories: publications, conferences, other activities. **Publications:** Typically, the average HRB contribution towards publication costs is €1,750/per article or **HRB Open Research**: rapid open peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee. (www.hrbopenresearch.org) free of charge. **Conferences:** We envisage that conference costs will be typically around €500/year for national conference and €1,500/year for international conference.
6. 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.
7. Travel Grant/Research Experience Abroad	A contribution to the costs associated with travel and accommodation to avail of the opportunity to gain research experience abroad. This should be clearly aligned with your overall research project and should be linked to your training and development plan.

8.1 Additional guidance to 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 further explain

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

[20] https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/open-access/

9 Other Funding

Please indicate if you have submitted this, or a similar application, to another HRB scheme or funding body. If this application has been submitted elsewhere, please indicate which HRB scheme or funding body, project title, result of submission or when outcome is expected and the amount of award. The word limit is **300 words**.

10 Ethical Approval

Ethical approval is required for all research work funded by the HRB that involves human participants and human material (including tissue). Applicants are responsible for ensuring that all necessary approvals are in place prior to the start of the research.

Applicants should allow sufficient time to obtain ethical and/or competent authority approval as a copy of such approvals must be submitted to the HRB before the initiation of the award. It is suggested that these are sought in parallel to the submission of the application to the HRB.

11 Supporting Documentation

The following documents must be uploaded to complete the application:

Mandatory documents:

- Letter of Support to LA from the current clinical employer
- Letter of Support from the HI
- Objectives and Deliverables Gantt Chart
- Research and Professional Development Gantt Chart.

If applicable:

- Project Description Support file - A maximum of 5 figures which can be a combination of images, graphs, tables, scales, instruments, or surveys
- Collaboration Agreement Form(s) – required for all collaborators
- Infrastructure Agreement Form(s) – required for biobanking and access to Clinical Research Facilities
- Letter of endorsement for medical doctors applying for new consultant contracts
- Letter of support from Sponsor Abroad.

12 Submission of Applications

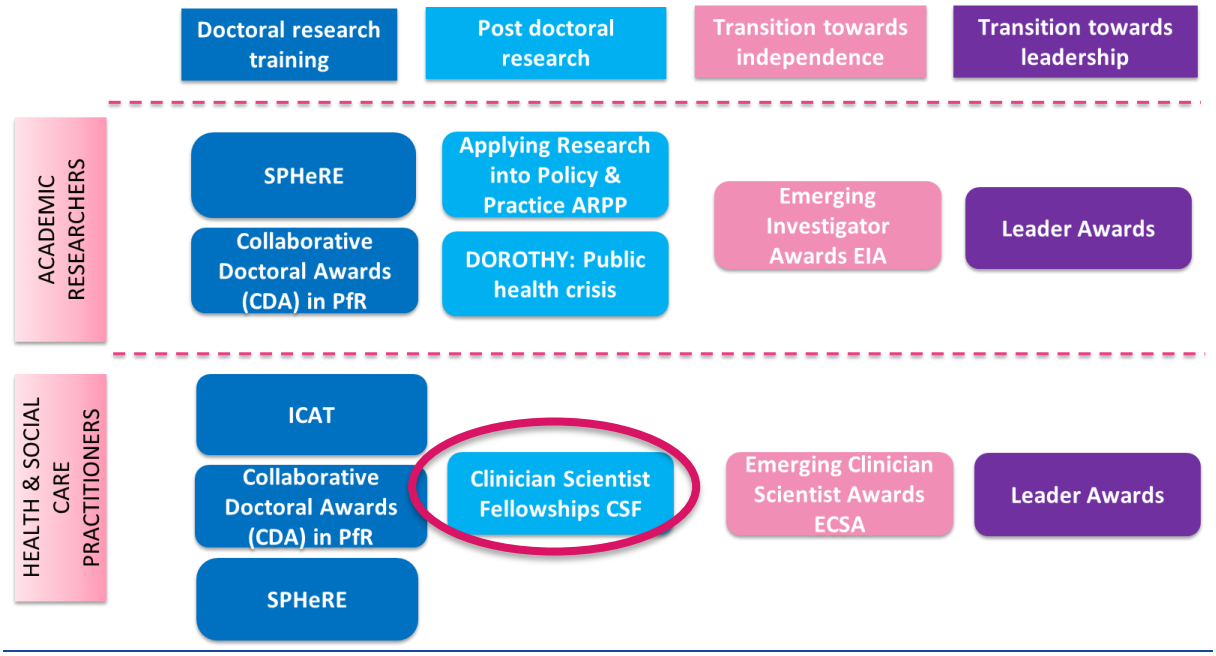
The deadline for submission of complete applications is **02 March 2023 at 13:00**.

1. After successful validation, the LA may submit the application. It will then be routed to the designated signatory at the HI for their approval.
2. If a signatory rejects the application the LA will be notified, along with any feedback the signatory has supplied.
3. The application can then be re-submitted; it will be returned to the signatory and will continue through the approval process as before.
4. On completion of the final approval by the HI signatory, a grant application number is assigned to the application.
5. The application automatically gets submitted to the HRB through GEMS for consideration for funding.

Please note that the HRB will not follow up any supporting documentation related to the application, such as HI's Letters of Support, Collaborator Agreement Form, Gantt charts etc. It is the responsibility of the LA to upload all supporting documentation prior to submission. If the documentation is not received by the HRB on time, in the correct format or is not properly signed or submitted, the application will be deemed ineligible without further review.

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's policy on ineligibility decisions is available at Appealing ineligibility decisions in funding schemes (hrb.ie).

Appendix II: HRB Research Career Pathways for Academic Researchers and Health and Social Care Practitioners



Appendix III: 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[21]. 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.

[21] 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 HI. The PPI Ignite Network Ireland has offices located in the following seven HIs: 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[22] and open publishing directly through the HRB Open Research platform[23]. 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[24] 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[25], 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.

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

[23] https://hrbopenresearch.org/

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

[25] 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 HI.

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 **General Data Protection Regulation** (GDPR) came into force on 25 May 2018. As a result, the applicant team will be asked through the HRB online grant management system GEMS to **confirm you understand** that personal data provided as part of this application, including but not limited to CV information, may be shared with person(s) based outside of the European Economic Area (EEA) for the specific purpose of obtaining peer reviews of this application. International reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Individual peer reviewers are selected for their specific expertise in relation to submitted applications and can be based anywhere in the world.

Furthermore, by confirming participation, you will be asked to confirm you understand that HRB uses the information you provide (regarding all applicant team members) 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, HI, 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)[26]. These regulations outline the mandatory suitable and specific measures

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

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[27].

DORA

The HRB is a signatory of DORA (San Francisco Declaration of Research Assessment) and has revised the LA's and the research team sections in many funding schemes. We ask additional questions addressing (1) contribution to knowledge, (2) contribution to research and career development of other researchers, (3) contribution to the wider research community and society and (4) a personal declaration. The aim is to provide additional information on the value, quality and impact of the applicant's work and the suitability of the applicant to the funding scheme and the research project proposed.

Although the HRB has never guided reviewers to consider impact factors or H-index, we now explicitly guide reviewers to assess the track record of the LAs and research team based on:

- The content, quality, and impact/influence of the research outputs in the research field and/or in policy and practice.
- Different types of research outputs in addition to articles (e.g. research data and datasets, research material, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence to health policy and practice, outreach and/or knowledge exchange activities, media coverage or other relevant activities).
- Active research experience of the LA. In this case career breaks should be taken into consideration and appropriate adjustments made when considering the record and impact of outputs.

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.

[27] https://hrcdc.ie/

HRB Gender Policy

In line with international best practice, the **HRB Gender Policy**[28] recognises the responsibility of the HRB to support everyone to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. To ensure fairness and equality to all applicants, each funding application received will be assessed as outlined in the call guidance documentation for that particular funding round. To ensure gender balance in decision-making, the HRB aims to reach the international best practice target of 40% of the under-represented gender in all HRB panels where possible. Gender will also be considered when appointing the position of Panel Chair.

Conflict of Interest

Conflict of interest rules *are applied rigorously*. Where a conflict of interest exists, the reviewer is requested to inform the HRB immediately so that an alternative reviewer may be appointed. International peer reviewers will not provide comments or scores on any application on which they have a conflict of interest.

Reviewers must adhere to high standards of integrity during the peer review process. They must respect the intellectual property of applicants and may not appropriate and use as their own, or disclose to any third party, ideas, concepts, or data contained in the applications they review.

Appeals procedure

The HRB's procedure for appealing ineligibility decisions in funding schemes is available at https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/appealing-ineligibility-decisions-in-funding-schemes/

The HRB's procedure for appealing funding decisions is available at *http://www.hrb.ie/funding/funding-schemes/before-you-apply/relevant-policies/.*

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[29] and Retention Policies[30].

[28] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-gender-in-research-funding/

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

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

Appendix IV: 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/