HEALTH RESEARCH BOARD

Clinician Scientist Postdoctoral Fellowships 2020 (CSF)

Building the capability of health and care practitioners at post-doctoral level

Guidance Notes

Key Dates & Times	
Applications Open	**19 August 2019**
Application Closing Date	**07 November 2019, @ 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 according to the timeline listed above. Applicants are strongly recommended to read the 'Detailed guidance notes for applicants', appended to this document prior to completing the application form.*

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Clinician Scientist Postdoctoral Fellowships (CSF) 2020

Guidance Notes

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1. Overview

The overarching aim of the Clinician Scientist Postdoctoral Fellowship (CSF) scheme is to support health and care practitioners from various professional backgrounds at postdoctoral research stage, and further develop them as clinician scientists. The fellowship will provide a unique opportunity to conduct research through a mentored post-doctoral period in a cross-sectoral and preferentially cross-disciplinary environment. The scheme will support the conduct of applied health research studies in areas of importance at local, national or international level.

Each fellowship will provide backfill funding for 50% FTE of the awardee for protected research time and funding for research-related costs. Each fellowship will have a duration of four to five years. The HRB envisages making between eight and ten awards in this round.

2. Introduction

The Health Research Board (HRB) *Strategy 2016 – 2020: Research. Evidence. Action.*[1]launched in January 2016.

One of the key actions of the HRB strategy is to support individuals during the mid-stage of their research career. In line with this strategic objective and the recently revised health research career path dedicated to health and care practitioners, the HRB is now inviting applications for its 2020 Clinician Scientist Postdoctoral Fellowships (CSF) scheme.

[1] http://hrbstrategy.ie/

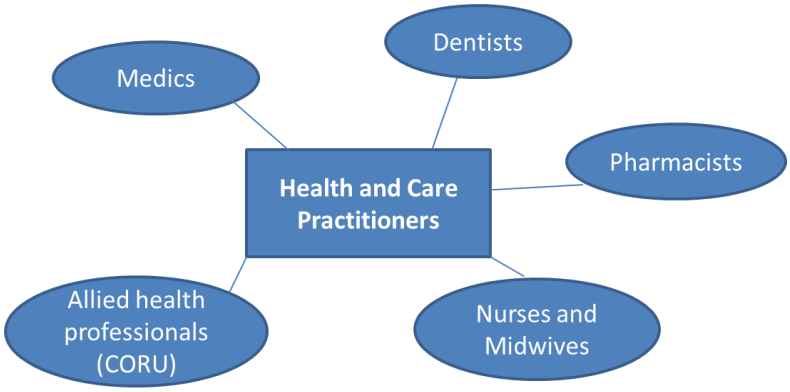

Figure 1: Health and care practitioners include individuals from various professional backgrounds.

This scheme targets health and care practitioners of any professional background who have just completed their PhD or have a PhD and some post-doctoral research experience but still need to consolidate and progress their research skills and knowledge to further advance towards a more independent research career. The career stage supported through this initiative is R2, postdoctoral research through to consolidation and/or progression as shown in Figure 1.

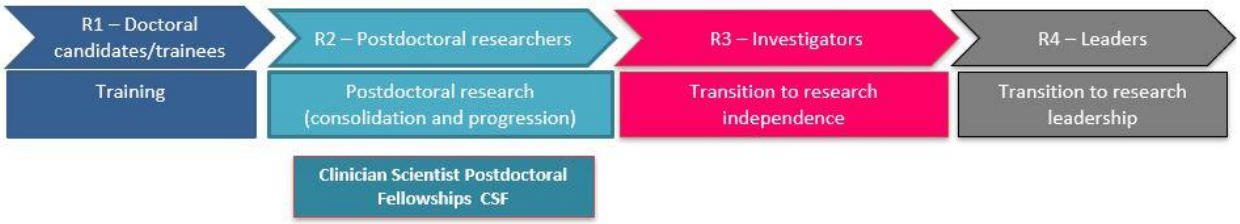

Figure 2 – Schematic representation of the career stage targeted by the CSF scheme within in the HRB research career path for Health and Care Practitioners.

An overview of the different funding schemes along the HRB research career path for health and care practitioners can be found in Appendix I.

3. Aims and objectives

The **overarching aim** of the CSF scheme is to support and further develop **health and care practitioners** as clinician scientists through a period of mentored postdoctoral research.

The scheme particularly emphasises the ability to apply research evidence to improve healthcare and health policy, reducing the gap between research findings, health policy and clinical practice.

For the purposes of this call and as defined in the research career path for health and care practitioners, a **clinician scientist** is defined as a health and care practitioner who is trained both in research and in a clinical profession

who conducts research alongside clinical practice. Clinician scientists have a unique role in bridging health research and clinical practice.

The **main objectives** are:

1. To enhance the capability of health and care practitioners in health research at postdoctoral level;
2. To support health and care practitioners to consolidate their research skills and expertise after their PhD and to progressively develop themselves as more independent clinician scientists;
3. To promote research projects with inter-sectoral collaborations (academic and health-related organisations or others) as well as cross-disciplinary and team-based approaches as relevant to the research question to be addressed and to apply and transfer research findings into policy and/or practice;
4. 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:

- Establish new collaborations and partnerships, including with those 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.

4. Scope

The call focuses on **applied health research** in areas of importance at local, national or international level (as opposed to fully investigator-led research). Research projects should have a strong potential to make research findings applicable and transferable into improved healthcare and policy.

The case for the selection of a research topic will need to be justified by

- demonstrating a documented need (for example see https://health.gov.ie/policy/) supported by systematically gathered evidence and
- demonstrating the ability to bring together a team (mentor and collaborators) that has the potential to influence policy and/or practice in this area (e.g. one or more of the team members should be an innovator[2]).

[2] ***Innovators*** *are broadly defined as individuals who have the skills, competencies and specific authority to bring together ideas – new, old or a combination of both – and translate these ideas into practical applications and/or solutions. They may be health researchers, health professionals, health policy managers, decision-makers or other knowledge users but they must have the authority, a track record of key*

We expect that evidence supporting the case for specific topics 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. Research projects should have a strong potential to make research findings applicable and transferable into improved healthcare and policy.

Lead Applicants are welcome to propose research projects related to other ongoing research studies within the scope of this call.

For the purposes of this scheme the following definition are used:

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.

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.

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 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.

The scheme will fund evaluation designs (e.g. experimental, quasi-experimental and observational designs). However, given the separate DIFA call, experimental designs (randomised trials) are limited to the following situations:

- The development of an intervention. This can also include initial testing of the intervention to provide proof of concept data, with the aim of developing a feasibility study for a future randomised trial (beyond this project);
- Evaluation of approaches to knowledge translation;

collaborations and expertise to influence changes and translate and/or implement knowledge into policy and practice, or towards a product.
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- Health services research and population health research interventions that are conducted in real-world settings, making research findings applicable and transferable into improved healthcare practice and policy, and readily interface with existing services or the planned rollout of new services in Ireland. The applicant may propose to conduct a feasibility study or the full intervention. In the latter case the applicant must provide evidence of feasibility. All interventions need to demonstrate a low risk/benefit ratio.
- Where the research project is an evaluation of health services research and population health research intervention, the scheme will also support Studies Within A Trial (SWATs) to explore primary trial methodology questions as a component of the overall research project. These must be costed within the funding envelope provided. A SWAT is a self-contained research study that has been embedded within a host study with the aim of evaluating or exploring alternative ways of delivering or organising a particular process. Given the dependencies of the SWAT to an intervention and the risks and challenges associated, if planning to apply for a SWAT please liaise with the HRB-TMRN (**https://www.hrb-tmrn.ie/**) and/or one of the HRB funded CTN for advice and support and also in order to minimise any potential risk.

*We adopt the concept of feasibility for a future definitive trial as described by Eldridge et al (2016). Eldridge describes 'feasibility' in preparation for a randomised controlled trial as an overarching concept, within which we distinguish between three distinct types of studies (1) randomised pilot studies (2) non-randomised pilot studies and (3) feasibility studies that are not pilot studies.
This call is open to all types of stand-alone feasibility studies conducted in preparation for a future definitive intervention.

This scheme will <u>not</u> 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 intervention (feasibility or definitive);
- Stand-alone systematic reviews or other evidence synthesis (only);
- Applications which are solely or predominately health service developments or implementation of an intervention without a predominant research element. The HRB will not fund the cost of providing the service or intervention itself, only the research element;
- Applications which are solely literature 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.

5. Funding and duration

Each award will provide support for four to five years. Applicants are strongly advised to engage with their prospective mentor(s) to discuss their needs during the fellowship to further develop themselves as clinician scientists.

Funding will support:

1. **Salary-related costs** for 50% FTE of the salary-related costs of the Lead Applicant. The HRB funding will cover the corresponding FTE of the salary-related costs of the locum replacement of the lead applicant in line with the appropriate scale;
2. **Research-related costs** at a maximum value of 50K to include:
    - 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.

More guidance on the budget can be found in Appendix II.

Note: HRB Fellowship schemes will not provide funding for overheads.

6. The Lead Applicant

Lead Applicants

Lead Applicants must be **health and care practitioners** from various professional backgrounds who have completed their PhD degree and who are currently (or will at the time of the award be) engaged in delivering clinical care. At this stage of their research career individuals will aim to increase the breadth of research knowledge, skills, methodologies and capabilities as well as establishing strong cross-border collaborations and networks.

Lead applicants can be individuals who are currently:

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

Notes:

(1) Lead Applicants 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 delivering health care are not eligible to apply to this scheme and should apply to the other HRB postdoctoral scheme **HRB Postdoctoral Fellowships (2020) - Applying Research into Policy & Practice (ARPP)**. This scheme is part of the revised **research career path dedicated to academic**

researchers. If you are not sure which scheme is more suitable for you to please contact the HRB. Please note you cannot apply to both fellowship schemes.

(2) For health and care practitioners with sufficient postdoctoral experience, who are ready to transition to research independence, the next round of the **Emerging Clinician Scientists Awards** is currently expected to open in 2021.

Lead applicant's suitability

Lead applicants should have appropriate research experience and track record demonstrated by having:

- A track record of research contribution to scientific knowledge demonstrated by relevant research outputs as leading author (e.g. first author).The HRB has signed up to **DORA** and we ask reviewers to consider the value, quality and impact of the applicant's work. Lead applicants should list their research outputs such as peer-reviewed publications research data, datasets, research material, databases, audio/video products, national and/or international reports or briefs, models and protocols, software, evidence of influencing policy and/or practice, outreach and/or knowledge exchange activities, media coverage or other research-related relevant activities;
- Some experience in communicating research outputs (e.g. conferences, presentation at institutional level, etc.);
- Shown potential in establishing collaborations including cross disciplinary, international and inter-sectoral, where relevant;
- Some experience in, or the potential to, apply 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.

Once funded, Lead Applicants will be responsible for the scientific and technical direction of the research project. S/he has 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.

Lead Applicant's Eligibility

A Lead Applicant must:

- Be an EU citizen or, if from outside the EU, have (or will have) a permanent Irish resident status or a valid work permit;
- Have a PhD or equivalent;
  - ***PhD Equivalence*** *is defined as having a minimum of four years active research experience post-primary degree.* ***You must call the HRB office to confirm your eligibility before applying;***
- Have completed his/her professional training (medics need to have completed their general training and may be at specialist registrar level);
- Hold (or will hold at the time of the award being made)
  - a clinical post in the Irish health service which covers or will cover the duration of the award if successful (e.g. specialist registrar*, hospital consultant, nurse practitioner, physiotherapist, private dentist practice);

or

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

or

- ❖ a joint clinical and academic teaching/education position without a research element within a Higher Education Institution and the Irish Health Services;

or

- ❖ If not currently working in Ireland, have the support of a HRB approved Host Institution and have already obtained or are negotiating a clinical post in the Republic of Ireland.

- Only apply to one HRB postdoctoral fellowship scheme (ARPP 2020 or CSF 2020).

Applicable to medical doctors only:

- 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 Host Institution** 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 50% protected research time supported by the HRB and 50% 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.
- Medical doctors applying at SpR level and who envisage to apply to consultant post during the fellowship are still eligible to apply even if the clinical contract will not cover the full duration of the award. At the time to applying for a new consultant contract they must have **the endorsement of the Head of Medical School** from the Host Institution and provide to the HRB. See above.
- Medical doctors **with a hospital consultant post should not ideally provide private practice** during the award.
    - Only Type A contracts will be allowed for individuals obtaining new consultant contracts.
    - The HRB expect 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.

Lead Applicants **must not** 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. Please note that fellowships and other individual awards (e.g. career development awards) are allowed;
  and/or
- ❖ Having already established a research team by supervising and mentoring early stage researchers as primary supervisor.

In either or both instances the Lead Applicants are not eligible to the fellowship scheme.

Notes:

(1) ***Active research experience*** *will be considered when assessing the Lead Applicants 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.*

(2) *Where an applicant fails to meet eligibility criteria, or the remit of the application is outside the scope of the scheme, the application will be deemed ineligible and will not progress to the next stage. Applicants will be informed accordingly.*

7. The Research Team

The application should have **inter-sectoral** and/or **cross-disciplinary**[3] and/or **international** contributions within the research team as appropriate to address the research question and to apply the research findings into policy and/or practice. The Lead Applicant is encouraged to collaborate with partner organisations such as hospitals, health agencies, universities, local government, voluntary organisations and/or industry.

Where relevant, experts in similar or different disciplines, such as, but not limited to, statistics, health economics, health service research, behavioural science, qualitative research methodologies, sociology etc., should be included as Official Collaborators. Experts by experience such as patients, potential patients, service users or carers are welcome to be included in the research team.

The selection of a mentor, who can demonstrate expertise in applied research, capacity building and coaching, will be crucial for the successful fellows.

Mentor

The Lead Applicant must nominate a **mentor** who will provide support and guidance during the application process and throughout the award. This will increase the likelihood of the fellow to progress through the research career phase and meet the objectives of the call.

The mentor should be an established and independent investigator in a post at the Host Institution. The mentor must have evidence of:

- Expertise and a skillset in advancing knowledge and research application into policy and/or practice;
- Leadership;
- Track record in scholarly publication, communication and knowledge exchange (such as peer-review articles, book chapters, national or international briefing/reports, workshops, policy dialogues, PPI, etc.);
- Coaching and mentoring.

[3]**Cross-disciplinary research** indicates research that involves more than one discipline. It is appropriate, if required, to use different approaches, such as multidisciplinarity and/or interdisciplinarity and/or transdisciplinarity, to address a specific research question and/or to respond to the objectives of a given scheme (e.g. capacity building and training)**.**

Collaborators

An Official Collaborator is an individual or an organisation who will have an integral and discrete role in delivering the 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 a Collaborator if they are providing specific contributions (either direct or indirect) to the activities. Collaborators can come from a range of backgrounds, for example 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 is not mandatory to have a total of 10 Collaborators. This is an upper limit and is available to allow flexibility if required.*

Public and Patient Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public in the research that we fund[4]. We use the INVOLVE UK (**www.invo.org.uk**) definition of the term 'public' which includes patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Public involvement, as defined here, is distinct from and additional to activities which raise awareness, share knowledge and create a dialogue with the public and it is also distinct from recruitment of patients/members of the public as participants in research.

'Public involvement' represents an active partnership between members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research.

Involving members of the public in research can improve quality and relevance. 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
- make the language and content of information such as questionnaires and information leaflets clear and accessible
- help to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants
- 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
- 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.

In the application, you are asked to describe any public involvement in your research throughout the various stages of research design, conduct, analysis and dissemination. We recognise that the nature and extent of active

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

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. The HRB will aim to provide specific feedback to applicants on the quality of their PPI plans through a public review process. The HRB will share the public review feedback with the PPI Ignite team in the Host Institution where applicable.

8. FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB supports **open research**[5] and open publishing directly through the **HRB open research platform**[6]**.** The HRB is now 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[7] provide guidelines 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 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.

Note: *As of January 2020, the HRB will be enforcing a new 'Data management and sharing policy'. As part of this policy, Data Management Plans (DMP) will be required from all successful HRB-funded projects. The HRB is developing a DMP template to be used by all HRB grantees from this date onwards. Although not currently mandatory, this template will be available soon through the Digital Curation Centre in UK - DCC Online and will be free to use by all HRB-funded researchers to ensure data management practices in health research are of high quality. This will be available before these awards are made.*

9. Training and Professional Development

The CSF fellowships are personal research awards and are not intended merely as 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 lead applicant 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.

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:

[5] http://www.hrb.ie/funding/policies-and-principles/open-research/
[6] https://hrbopenresearch.org/
[7] https://www.nature.com/articles/sdata201618

- 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 may not be competitively reviewed.*

10. Host Institution and other support

Host institution

The **Host Institution** for the award should be a recognised research organisation in the Republic of Ireland. This is normally that of the Lead Applicant and/or the mentor.

The Host Institution for the award must be on the HRB list of approved Host Institutions (see **http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/**).

Support from Clinical Research Infrastructures

Applicants are expected to avail of advice, data management services and/or other forms of support from existing research infrastructures such as a Clinical Research Facility/Centre (CRF/CRC), Centre for Applied Medical Imaging (CAMI), HRB Clinical Research Co-ordination Ireland (HRB CRCI), the HRB Trials Methodology Research Network (HRB TMRN) and/or a thematic HRB Clinical Trials Network (HRB CTN).

11. The General Data Protection Regulation (GDPR)

The **General Data Protection Regulation** (GDPR) came into force on 25 May 2018. As a result the applicant team will be asked through 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 the 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, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended we will continue to keep your information on file (in accordance with HRB policies) to allow us to evaluate the outcomes, outputs and impacts of HRB investment in your research.

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

12. Application and review process

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

- GEMS will close the full application form for this scheme automatically at 13.00 on **07 November 2019**.

The application must have been reviewed and approved by the signatory approver at the research office (or equivalent) in the host institution 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 host institutions 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.

The HRB has recently signed up to **DORA**[8] (San Francisco Declaration of Research Assessment) and has revised the lead applicant's and the research team sections in all the funding schemes supporting research careers and we now ask questions, such as personal declaration, most important contributions to scientific knowledge and/or additional expertise matching the role in the application with relevant research outputs, and synergistic activities. They aim 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 all reviewers to assess the track record of the lead applicants 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.

[8] **https://sfdora.org/**

- Different types of research outputs in addition to peer-reviewed articles (e.g. research data and databases, research material, 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 Lead Applicant, so career breaks should be also taken into consideration and appropriate adjustments made when considering the record and impact of outputs.

Phase 1 – International Peer Review, Public Review and Shortlisting

The applications will be checked for the eligibility of the Lead Applicant and the scope of the project. Ineligible applicants will be notified at this stage and their applications will not be sent to review.

There will be a two-step shortlisting process for all eligible applications, which aims to increase the effectiveness of the review process and its outcome:

Step 1

For each eligible application the HRB aims to receive written feedback from at least three international peer reviewers and two public reviewers. 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 proposal, they will provide comments but will not provide a score. The individual scores received from the international peer reviewers for each application will be averaged by the HRB and a preliminary short list compiled. A higher number of Lead Applicants will be selected in this step than can be interviewed for further review by an international shortlisting panel.

Step 2

An international shortlisting panel with approximately 10-12 members and an independent Chair will be sought. Panel members will be selected based on the scope of the scheme and the skills and expertise required (e.g. research area and methodological and analytical approaches, coaching and mentoring, knowledge translation/applied health research, etc.).

Three panel members will review each application and the related peer-reviewers' comments shortlisted in step 1. They will provide comments and indicate if they rate this applicant to be competitive at interview or not. Panel members will virtually review several applications and so will have a good overview of the field of applicants. We hope that bringing in the views and judgement of the shortlisting panel earlier in the review process will make shortlisting more effective. An independent Chair will work closely with the HRB to oversee the overall shortlisting process. All applicants will be notified after the second step of the shortlisting which will be approximately four weeks prior to the interview panel meeting.

The dates of the interview panel meeting, provisionally scheduled for early June 2020, will be notified to all Lead Applicants in October-November 2019.

Phase 2 – Interviews with International Panel

Approximately seven to eight members from the shortlisting panel will be invited to be part of the interview panel. Applicants will have access to the peer and public reviews of their application prior to the interview and should aim to address any concerns raised by peer reviewers and any major concerns raised by public reviewers. In addition to the peer review the interview panel will also have access to public reviews ahead of the interview date.

Each interview will begin with a short PowerPoint presentation from each candidate followed by Q&A session. Panel members will be assigned as primary and secondary interviewers to specific applications. More details on the interview will be provided to the shortlisted candidates.

The peer-reviewers and panel reviewers will assess all applications based on the following assessment criteria, as approved by the HRB Board, and successful applications will be expected to **score highly in all criteria**.

1. **Standing and potential of the Lead Applicant to progress towards independence**
2. **Suitability and breadth of the research team and mentor;**
3. **Strategic relevance of the research project to policy and/or practice needs, including the potential for application of the research findings;**
4. **Appropriateness of the research approach and methodologies;**
5. **Feasibility of the project.**

The PPI 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

Public Reviewers are asked to comment on the following:

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

The recommendations of the Interview Panel are 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 candidates to notify them of the outcome. It is estimated that the time from the deadline of the call to the HRB decision after the assessment will be approximately eight months.

Note: *The main aim of the scheme is to build capacity among health and care practitioners at postdoctoral level in applied health research. Therefore,* ***when ranking fundable applications with the same score*** *those from less represented professional backgrounds will be prioritised.*

*The **HRB Gender Policy** came into effect on 1 June 2016[9]. Gender balance of the Lead Applicant will be among the second ranking factor to prioritise proposals with the same scores in the Interview Panel ranking list.*

The HRB will aim to provide specific feedback on the review process to all applicants. Feedback on the quality of their PPI plans as reviewed through a public review process will also be provided. The PPI review does not constitute a formal scoring criterion in this round, however it may influence discussions under each assessment criterion as relevant to the project.

13. 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 are required to respect the confidentiality of the peer review process, which is designed to protect and preserve the integrity of the HRB's advisers and processes. Reviewers may not discuss any aspect of the scoring or assessment with applicants or colleagues. All such requests must be referred to the HRB.

14. Timeline

Key Dates	
19 August 2019	Call opening
7 November 2019 @1pm	Call closing for applications
End of November 2019	Eligibility completed
End of November – End of March 2020	International Peer-review and 1st stage shortlisting
End of March-Early May 2020	Panel review and 2nd stage shortlisting. Selected candidates are invited for interview. All Lead Applicants will be informed on the shortlisting outcome in early May.
First week June 2020	Two-day Panel interview meeting
End June 2020	Board Approval and outcome notification
July – October 2020	Budget negotiation and contracts issued and signed
01 November 2020 onwards	Start of awards

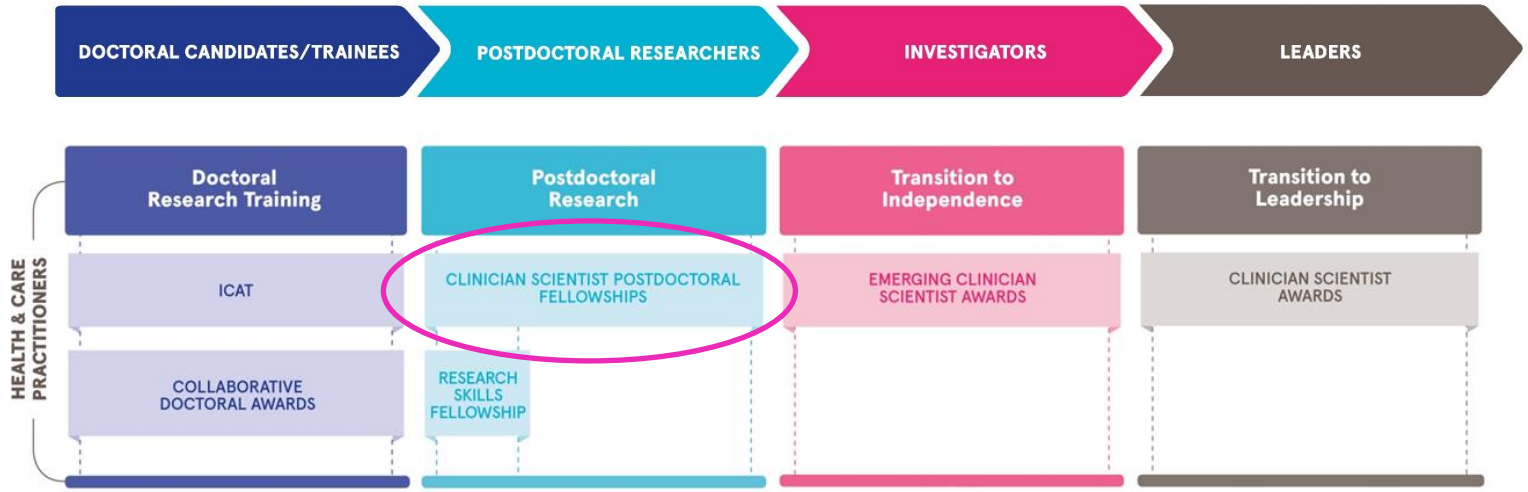
[9] **https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-gender-in-research-funding/**

15. Contact

Dr Anne Costello
Project Officer - Pre-Award
Research, Strategy and Funding Directorate
Health Research Board
e **acostello@hrb.ie**
t +353 1 2345 157

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's procedure for appealing funding decisions is available at http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/

Appendix I – Overview of the HRB Research Career Path for Health and Care Practitioners (developing Clinician Scientists)



Appendix II: 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 for further information.

The Lead Applicant must create the application, but it can then be jointly completed with named co-applicants.

- Lead Applicants can register on GEMS and they will receive an email to confirm their registration and log in details. The Lead Applicant can then add information on their contact and CV details in the 'Manage My Details' section of GEMS.
- Lead Applicants previously registered on GEMS can log in 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.

Then the LA will be asked to go through a check list of mandatory **Yes/No** questions. In order to start the application, the LA must satisfy the conditions of this check list.

Lead Applicant Eligibility	
Please confirm you are an EU citizen or, if from outside the EU, have (or will have at the time of the award) a permanent Irish resident status or a valid work permit	✓
Please confirm you have a PhD or equivalent. Please see pages 9 and 10 of the Guidance Notes for further information.	✓
Please confirm you have completed your professional training (medics need to have completed their general training and may be at specialist registrar level);	✓
Please confirm you hold or will hold at the time of the award being made (1) a clinical post in the Irish health service **or** (2) clinical post in private practice **or** (3) a joint clinical and academic teaching/education position which covers or will cover the duration of the award if successful.	✓
Please confirm you have not been in receipt of 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. Please note that fellowships and other individual awards (e.g. career development awards) are allowed.	✓

Please confirm you have not yet established a research team or have supervised/are supervising and mentoring early stage researchers as primary supervisor.	✓
Please confirm that you will not apply to ARPP 2020.	✓
Application Scope Eligibility	
Please confirm the application falls within the scope of Population Health Research (PHR), Health Services Research (HSR) or Clinical Research as outlined on page 6 of the guidance notes.	✓
Please confirm the application does not include any item listed under out of scope items not funded by this scheme on page 7 of the guidance notes.	✓
Other Requirements	
By submitting this application, I agree 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 2020 Guidance Notes.	✓

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

Contents

Host Institution

A *HRB Host Institution* is a research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all of the HRB's award schemes. The **Host Institution for the award** is normally that of the Lead Applicant but it may be another organisation/institution designated by the research team, where it is clearly justified. Information is available on the HRB website on the current approved Host Institutions and on the application process for research performing organisations to be approved as HRB Host Institutions[10].

In GEMS you will be asked to identify a Host Institution (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 Host Institution, 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 Host Institution approvals.

Signatory Notification (within Host Institution)

Once the Host Institution is selected at the initial stages of application creation this will allow the Lead Applicant to notify the authorised signatory (Dean of Research or equivalent person authorised to endorse research grant applications for the Host Institution) in that Host Institution of the Lead Applicant's intention to submit an application to the ARPP 2018 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 for the **full application** as soon as possible in the application process. The signatory will receive an email from GEMS with the name and email details of the Lead Applicant and if they have any queries or clarifications they can engage directly to resolve them. The HI signatory must confirm their willingness to participate as HI for the full proposal 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 of the full proposal for submission to the HRB.

1. Project Details

1.1 Project Title

This should be descriptive and concise and should reflect the aim of the project.

1.2 Acronym

Acronym is optional

1.3 Project Duration and Start date

Please indicate the expected length of the proposed project in months (typically in 48 months and max 60 months for part-time) and the proposed start date. The earliest start date is 01 November 2020.

[10] http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/

1.4 Type of Researcher

Please describe yourself as:

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

1.5 Current type of contract and part time arrangements

1.5.1 Please detail the type of contract you currently hold (e.g. full time clinical, academic consultant, etc). The word limit is **30 words**.

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

If **Yes**

- State percentage of research time currently protected, as a full time equivalent (%FTE)

1.5.3 Clearly specify and explain the nature of the time you wish to buy out during the fellowship (e.g. clinical including private practice and/or academic etc). **Please note the HRB will not buy out any protected research time you have in your current contract**. The word limit is **100 words.**

1.5.4 You must also clearly describe 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. Please note that part-time awards can be taken as 50% for research protected time. The word limit is **200 words**.

Letters of support:

(1) Letter of support from current employer in-practice: Lead Applicants must provide a letter of support on headed paper from the clinical organisation where they are providing clinical care and currently 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.

(2) 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 **must provide a letter of endorsement from the Head of Medical School at the Host Institution** 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.

1.6 Project Lay Summary

This lay summary is similar to the project abstract in that you are asked to describe what you propose to do, say why you think it is important to complete this piece of work 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. The lay summary may be used when providing information to the public with regard to the variety of research funded by the HRB and may be posted on the HRB website. The word limit is **300 words**.

1.7 Project Abstract

This should be a succinct summary of the proposed research question. The aims and hypotheses of the project should be conveyed with clarity. The objectives of the project and what the work is expected to establish should be described. Ideally it provides a clear synopsis of your proposal and should set the research proposal in context. The word limit is **300 words**.

1.8 Keywords

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

2. The Lead Applicant

Details are requested about the Lead Applicant including their position and status (contract or permanent) and their supervisory experience.

The Lead Applicant's **contact and CV details** (Name, contact information, institution, present position, employment history, profession and membership of professional bodies) **Funding Record details** and **Publication record detail**s are managed in 'manage my details' section of GEMS. The Funding details and publication record are automatically included in any application created involving that individual.

2.1 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 both women and men 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.*

2.2 ORCiD

The HRB is not yet an ORCID member, however we are encouraging all researchers to obtain this persistent digital identifier that distinguishes you from every other researcher. Lead applicants are encouraged to include an ORCID iD in their application. Please note this is not a mandatory field for submitting your application. For more information and to register please see http://orcid.org/

2.3 Career breaks

Please reference any gaps to your past productivity. You may include a description of factors (e.g. career break, flexible work arrangement, other family care responsibilities, illness, disability, and change in sector (e.g. academia to private sector) or discipline. The word limit is **150 words**

2.4 Research Outputs and Contribution to scientific knowledge

Please reference **up to five research outputs that had most impact on your research career to date.** Please explain very briefly for each research output (four-five lines) the research question, significance and impact of the contribution, your specific contribution and your career stage at the time. The word limit is **400 words**

Research outputs: Please note that the HRB has signed up to **DORA** and we ask reviewers to consider the value, quality and impact of the applicants' work. To this end we ask you to list research outputs such as peer-reviewed publications, research data, research material, databases, audio/video products, national and/or international reports or briefs, models and protocols, software, evidence of influencing policy and/or practice, outreach and/or knowledge exchange activities, media coverage or other relevant research-related activities.

2.5 Personal declaration

Please describe (1) why you are well suited to this fellowship, (2) how this fellowship will further progress your research vision and career trajectory and (3) how your expertise to date and the proposed personal development plan proposed will help you to achieve the main objectives of this call. The word limit is **300 words**.

2.6 Synergistic Activities

Please provide some examples under the headings below that demonstrate the broader impact of your professional and academic activities to date. Please note that the inclusion of these items aims to provide a more rounded and holistic recognition of your career to date. The assumption is that not all researchers will, necessarily, have experience under all of these headings. These activities will be assessed in the overall context of the targeted career stage and the objectives of this scheme. The word limit is **300 words.**

- **Research process** Activities such as stakeholder engagement/PPI, collaborative & cross disciplinary research, research integrity and risk management in open science procedures (e.g. making research outputs including data openly available, sharing data for reuse, etc.).
- **Societal Impact and outreach** Knowledge translation activities that best relate to the work described in your application. E.g. communication & dissemination (beyond publications), development of IP (patents, licenses), development of guidelines and standards, knowledge exchange and outreach activities.
- **Service to research community** Peer-review contribution, networking activities, memberships to committees and/or other relevant advisory groups
- **Leadership** Activities where you have shown leadership in academic and/or other professional activities (e.g. organisation of courses, journal clubs, etc)
- **Professional development** Continuing professional development, project management and personal qualities.

3. The Research Team

3.1 Collaborative and cross-disciplinary approach

The application should have **inter-sectoral** and/or **cross-disciplinary**[11] contributions in the research team as appropriate to address the research question and to apply the research findings into policy and/or practice. The Lead Applicant is encouraged to collaborate with partner organisations such as hospitals, health agencies, universities, local government, voluntary organisations and/or industry.

Where relevant, experts in similar or different disciplines such as, but not limited to, statistics, health economics, health service research, behavioural science, qualitative research methodologies, sociology etc., should be included as official Collaborators. Experts by experience such as patients, potential patients, service users or carers are welcome to be included in the research team

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 and/or inter-sectoral collaboration, if relevant. The word limit is **400 words**.

3.2 Mentorship arrangements

As Lead Applicant please describe why you have chosen this individual to act as your mentor and provide details of the arrangements you have made in order to receive support and guidance for the benefit of your career development, as well as the direction of the project. The word limit is **200 words**

3.3 Mentor

The Lead Applicant must nominate a **mentor** who will provide support and guidance during the application process and throughout the award. This will increase the likelihood of the fellow to progress through a research career.

The Lead Applicant can add the Mentor to an application by entering their name on GEMS. If the individual is already registered on GEMS, the system will find them and will allow the Lead Applicant 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 Lead Applicant to participate on the application as Mentor. A registered Mentor can decide whether to accept or reject their participation. If the proposed mentor rejects participation on an application the Lead Applicant is informed and may revise the application accordingly. When a Mentor accepts they will be able to complete the mentor sections of the application and they will also have the ability to 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.*

[11] As defined in the Framework for the Health Research Careers and for the purpose of this scheme, **cross-disciplinary research** indicates research that employs more than one discipline. It could use different approaches, such as **multidisciplinarity** and/or **interdisciplinarity** and/or **transdisciplinarity, to address a specific research question and/or to respond to the objectives of a scheme (e.g. capacity building and training).**

Prior to validation and submitting the application to the authorised signatory of the nominated Host Institution 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

The Mentor can manage his/her basic **contact and CV details** (Name, contact information, institution, present position, employment history, profession and membership details of professional bodies).

Please note that **Funding Record** (including HRB grants) most relevant to this application and **publications** will be requested manually in the application form so you do not need to enter or update them under manage my details.

Where research outputs are requested *please note* The HRB has signed up to **DORA** and we ask reviewers to consider the value, quality and impact of the applicant's work. The mentor should list research outputs such as peer-reviewed publications, research data and databases, research material, audio/video products, national and/or international reports or briefs, models and protocols, software, evidence of influencing policy and/or practice, outreach and/or knowledge exchange activities, media coverage or other research-related relevant activities. As such any requested research outputs can include the sources mentioned above as well as non-peer-reviewed publications such as policy briefs, national reports, research reports, evidence synthesis or other achievements such as honours/awards, national and international profiling, plenary lectures or invited speaker at international conferences and any expertise relating to commercialization and/or industry involvement, if relevant.

3.3.1 Please describe yourself as:

- Health and social care professional with a joint or full academic appointment
- Investigator
- Other, please specify

3.3.2 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 both women and men 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.*

3.3.3 ORCiD

The HRB is not yet an ORCiD member, however we are encouraging all researchers to obtain this persistent digital identifier that distinguishes you from every other researcher. Lead applicants are encouraged to include an ORCiD ID in their application. Please note this is not a mandatory field for submitting your application. For more information and to register please see **http://orcid.org/**

3.3.4 Mentor's most relevant funding track record

Please reference up to five peer-reviewed grant funding (including HRB ones) that are most relevant to this application. Specify the title, funding awarded, period and your role (Lead Applicant, Co-Lead Applicant, Co-Applicant or Collaborator).

3.3.5 Mentor's expertise statement and research outputs

Briefly describe why you are well-suited to the role of mentor of the Lead Applicant in this proposal by demonstrating evidence of expertise and skills in the following:

3.3.5.1 State **evidence** of your **leadership and collaborative role** throughout your career, including leadership roles, recognised national/international contributions, collaborations and partnerships with other researchers and key individuals, including those from other research disciplines, roles, and sectors. Please reference **up to four research outputs** most relevant to this role and the required expertise. The word limit is **400 words**.

3.3.5.2 Provide any **evidence of** expertise in relation to research outcomes that have been **translated into, and/or have influenced, health care practice and/or policy and/or service delivery**. You may also include here any expertise relating to commercialization and/or industry involvement, if relevant. Please reference **up to four research outputs** most relevant to this role and the expertise required. The word limit is **400 words**

3.3.5.3 Provide **evidence of capacity building, mentoring and coaching** you may have in relation to experience in team building, mentoring and supervising of researchers and how it has impacted upon the researchers' career. Particularly mention experience in providing support at early stage researchers (PhD) and mid-stage researchers (postdoctoral and research fellows) level and experience in mentoring / supervising individuals from outside your own discipline, if any. Please provide the numbers of current and completed MSc and PhD students, directly under your supervision, as well as numbers of previous and current post-doctoral or other researchers. The word limit is **200 words**.

3.3.6 Publications

Please provide the total number of peer-reviewed publications which you have authored and/or co-authored. You may add a weblink to your full list of peer-reviewed publications.

Please note this part must be completed by the Lead Applicant

3.4 Collaborators

The Lead Applicant can add up to 10 collaborators per application. Unlike co-applicants, the information for collaborators is not automatically drawn from the 'Manage my Details' section of GEMS but must be entered by the Lead Applicant. The Lead Applicant must enter **contact and CV details** for all collaborators including name, contact information, institution, present position, employment history, profession and membership details of professional bodies, **Publications and Funding Record** (if applicable) (5 most relevant publications in peer-reviewed journals and details of 5 past or current grants held (including HRB awards) relevant to this application where the collaborator has acted as Lead Applicant or Co-Applicant).

3.4.1 Collaborators' 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**

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. Electronic signatures are acceptable on letters/forms that are uploaded on GEMS.

4. Research Project Description

The Project Description must include:

4.1 Research Question
4.2 Case for Research
4.3 Systematically gathered evidence
4.3 Overarching Aim
4.5 Objectives and Deliverables (plus Gantt or alternative)
4.6 Detailed Research Plan
- 4.6.1 *Study type*
- 4.6.2 *Research Design and Methodological Approach*
- 4.6.3 *Studies within a Trial (SWAT), if applicable*
- 4.6.4 *Changes from previous submissions, if applicable*
- 4.6.4 *Project Management*
- 4.6.5 *Outline on FAIR Data Management and Stewardship*
- 4.6.6 *Dissemination and Knowledge Exchange Plan*
- 4.6.7 *Translational Pathway and Impact Statement*
- 4.6.8 *Public and Patient Involvement in the Research Project*

4.7 Project Description Support
4.8 References
4.9 Additional information on the research
- 4.9.1 *Potential Risks and Ethical Concerns*
- 4.9.2 *Gender issues in the research project*
- 4.9.3 *Arrangements for Sample Collection for Biobanking*

4.9.4 *Compliance with Data Protection Regulations*
4.9.5 *IP considerations*

4.1 Research Question

Clearly state the research question behind the proposed work. The word limit is **100 words**.

4.2 Case for the research

Please set out a case for the **relevance and importance** at local, national or international level to propose this research project at this time in Ireland. Please address the following:

- ✓ Outline the problem to be addressed and the relevance to the policy and practice (locally, nationally or internationally); please reference any document/publications;
- ✓ Include a description of any pilot work/data already undertaken or the use of existing national or international data;

Describe the anticipated outputs, outcomes and impact of the proposed research, particularly the potential to be applied on policy and/or practice. The word limit is **1500 words**.

Note: *Be aware that the peer reviewers and panel reviewers reading your application will be based outside of Ireland, so it is important to describe the current healthcare delivery context in Ireland when discussing issues around need and relevance.*

4.3 Systematically gathered evidence

Describe the systematically gathered evidence base for this research such as relevant systematic reviews and other formats of evidence synthesis.

Evidence synthesised systematically to include evidence of (i) a systematic identification of previous work, (ii) critical appraisal, (iii) synthesis of the evidence and (iv) interpretation of findings. Where no relevant published systematic review exists it is expected that the applicants will undertake a satisfactory review of the currently available evidence using systematic techniques. Simple literature overviews are not sufficient. Applicants must provide a protocol to show how the search was conducted, including literature and clinical trials registries.

The proposed standard for what constitutes a satisfactory review of the existing evidence to inform your research proposal is as follows:

- A relevant Cochrane Systematic Review **or**
- If no Cochrane Review exists, then another systematic review that is published in a peer reviewed journal **or**
- If no published systematic review is identified then the Lead Applicant and research team should present the findings of a systematic review that they have undertaken for the purposes of the application. Importantly, in this case applicants are required to provide sufficient details of the methodologies employed to allow evaluate confidence in the findings and to allow the review to be replicated. Simple literature overviews are not sufficient.

- Additional evidence may be provided through formal input from relevant Irish patients, service users or carers. However, this does not substitute for systematically gathered evidence.

The word limit is **750 words**.

Note: *Be aware that the peer reviewers and panel reviewers reading your application will be based outside of Ireland, so it is important to describe the current healthcare delivery context in Ireland when discussing issues around need and relevance.*

4.4 Overarching Aim

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

4.5 Objectives and Deliverables

Please add a minimum of 3 research objectives. Objectives should be SMART (specific, measurable, achievable, realistic and time-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 each deliverable**.

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.

Sample Gantt (edit as appropriate)	Project Year 1				Project Year 2				Project Year 3				Project Year 4			
Calendar Timeline																
Work Package 1: (Title)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1.1: e.g. literature review	◆															
1.2: e.g. ethics submission/approval		◆	◆													
1.3: e.g. staff recruitment/training	◆	◆	◆													
1.4: e.g. data collection		◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
1.5: e.g. data analysis					◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
1.6: e.g. dissemination														◆	◆	◆
Work Package 2: (Title)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
2.1:																
2.2:																
2.3:																
2.4:																
2.5:																

Legend
Time that work is expected to take place on a work-package/objective = ◆
Calendar Timeline: Shade boxes black up to current calendar date on project.
Work-package/objective progress: Shade boxes green up to current stage to indicate progress on objective to date. As in example above, this can indicate where project is ahead of schedule.

Figure 1: Example of Gantt chart template available from the HRB.

4.6 Detailed Research Plan

4.6.1 Study type

Please select a study type:

1. Research project within the remit of clinical, health services research and/or population health research;

2. Development of an intervention;
3. Evaluation of approaches to knowledge translation;
4. Evaluation of intervention (health services research and/or population health research only): feasibility or definitive trial of an intervention (with or without a SWAT).

Please note only the following types of evaluations are eligible:

- The development of an intervention (any type). This can also include initial testing of the intervention to provide proof of concept data, with the aim of developing a feasibility study for a future randomised trial (beyond this project);
- Evaluation of approaches to knowledge translation;
- Evaluation of health services research and population health research interventions that focus on making research findings applicable and transferable into improved healthcare practice and policy and interface readily with existing services or the planned rollout of new services in Ireland. The applicant may propose to conduct a feasibility study* for a future definitive trial or a definitive trial of an intervention. In the latter case, the applicant must provide evidence of feasibility. Any evaluation of an interventions must demonstrate a low risk to benefit ratio.
- Where the research project is an evaluation of health services research and population health research intervention, the scheme will also support Studies Within A Trial (SWATs) to explore primary trial methodology questions as a component of the overall research project. These must be costed within the funding envelope provided. A SWAT is a self-contained research study that has been embedded within a host study with the aim of evaluating or exploring alternative ways of delivering or organising a particular process. Given the dependencies of the SWAT to an intervention and the risks and challenges associated, if planning to apply for a SWAT please liaise with the HRB-TMRN (**https://www.hrb-tmrn.ie/**) and/or one of the HRB funded CTN for advice and support and also in order to minimise any potential risk.

4.6.2 Research Design and Methodological Approach

Summarise the proposed research plan, providing descriptions of individual project/work streams or work packages and describe how they integrate to form a coherent research proposal. 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.
The word limit is **4000 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 should 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.
- Identify facilities and or resources you will need access to, stating who the necessary Gatekeepers are and ensure such are included as Collaborators.
- Where research plans are linked and dependant in some way on larger national longitudinal or any larger studies, issues such as linkages, sustainability, resources etc. need to be addressed.
- 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.

Other useful links and resources are summarised in Appendix III.

THE FOLLOWING QUESTIONS ARE APPLICABLE TO EVALUATION OF INTERVENTIONS (FEASABILITY OR DEFINITIVE) ONLY

For applications proposing a feasibility study (with or without a SWAT)

4.6.2a Research Design and Methodological Approach

Justify the **choice** of your planned intervention. Describe and justify the **design** chosen, the methods you plan to use and the rationale of your choice. Importantly also address the risks and benefits of conducting the intervention.

In addition to describing the feasibility study, you must also provide a brief description of any information relevant to the planned intention to conduct an intervention study in the future with clear progression criteria, even though it is not part of this application.

Note: Please consider following the TIDieR[12] checklist and guide for describing the intervention and the PICO framework to frame the research question.

4.6.3 Are you proposing a Study within a Trial (SWAT)

If Yes

Provide full details regarding the type of analysis to be undertaken, the rationale of the design proposed, the personnel who will conduct, power calculations, inclusion/exclusion criteria and costings as appropriate.
The word limit is **500 words.**

You must also upload the (1) full protocol for the SWAT and (2) a letter of support from the Principal Investigator of the host trial confirming full support to your proposed SWAT, the current stage of the trial and the funding in place.

[12] *Hoffmann T et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014; 348:g1687*

For applications proposing an evaluation of definitive trial of an intervention (with or without SWAT)

4.6.2b1 Evidence from previous feasibility studies

Where available, include relevant information from previously conducted feasibility studies.
Please address all the following:

- Describe clearly but succinctly the work that was carried out, when, on what groups in which settings and what was learned that facilitated the finalisation of the protocol for the definitive intervention.
- Provide details on the accessibility to services, data, etc
- Provide assurances that you are confident that the intervention can be consistently implemented as intended.

The word limit is **500 words.**

4.6.2b2 Research Design and Methodological Approach

Justify the **choice** of your planned intervention. Describe and justify the **design** chosen, the methods you plan to use and the rationale of your choice. Importantly also address the risks and benefits of conducting the intervention.

Note: Please consider following the TIDieR[13] checklist and guide for describing the intervention and the PICO[14] framework to frame the research question.

4.6.3 Are you proposing a Study within a Trial (SWAT)

If Yes

Provide full details regarding the type of analysis to be undertaken, the rationale of the design proposed, the personnel who will conduct, power calculations, inclusion/exclusion criteria and costings as appropriate. The word limit is **500 words.**

You must also upload the full protocol for the SWAT and a letter of support from the Principal Investigator of the host trial confirming full support to your proposed SWAT, the current stage of the trial and the funding in place.

4.6.3 Changes from previous submissions

Has an iteration of the proposed research been submitted to any HRB award scheme in the last 3 years?
If Yes

- Please include the funding scheme and the year of previous submission.

[13] Hoffmann T et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014; 348:g1687

[14] Huang X, Lin J, Demner-Fushman D (2006). "Evaluation of PICO as a knowledge representation for clinical questions" (PDF). *AMIA Annu Symp Proc*: 359–63. PMC 1839740.

- 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 **500 words**.

4.6.4 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, if any, which are crucial to delivery of the project. Outline the processes that will be put in place to ensure that the project is well managed, commenting on project management, meetings schedules, financial management etc. The word limit is **600 words**.

4.6.5 Outline on FAIR Data Management

Describe the approach to data management and stewardship that will be taken during and after the project, including who will be responsible for data management and data stewardship. Please consider the FAIR Guiding Principles for scientific data management and stewardship: Findability, Accessibility, Interoperability, and Reusability[15].

With the support of data stewards or other data-related services support in the institution (typically library and ICT and digital service, etc) all Lead 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.

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.

[15] 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).

Note: *As of January 2020, the HRB will be enforcing a new 'Data management and sharing policy'. As part of this policy, Data Management Plans (DMP) will be required from all successful HRB-funded projects. The HRB is developing a DMP template to be used by all HRB grantees from this date onwards. Although not currently mandatory, this template will be available soon through the Digital Curation Centre in UK - DCC Online and will be free to use by all HRB-funded researchers to ensure data management practices in health research are of high quality. This will be available before these awards are made.*

4.6.6 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, shared and made openly accessible, in line with HRB Open Access Policy[1]. Research outputs include peer-reviewed 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[2].

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 are to 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.

The word limit is **500 words.**

Types of publication routes[3]:

- **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 paid 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**).

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

[2] 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.

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

4.6.7 Translational pathway and 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. The word limit is **600 words.**

Note: *Be aware that the peer reviewers and panel reviewers reading your application will be based outside of Ireland, so it is important to describe the current healthcare delivery context in Ireland when discussing issues around need, relevance, timeliness and feasibility.*

4.6.8 Public and Patient Involvement in the Research Project

The HRB recognises that the nature and extent of active public involvement is likely to vary depending on the context of each study. *Please note PPI does **not** include the recruitment of study participants. Whilst this falls under patient-oriented research, it is participation of the public rather than involvement. 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 III. Please be aware of the PPI Ignite offices in some host institutions.

Are you including public involvement in your application?

If **Yes**
What is the purpose of this involvement? Please **describe** (i) public involvement to date, (ii) how previous PPI has influenced/changed what work has been planned, and (iii) public involvement planned for the duration of the award (e.g., oversight, conduct, analysis and/or dissemination). This section should be a summary of public involvement activities. Please ensure to provide more detail in other sections as appropriate. Provide information on the individuals/groups and the ways in which they will be involved. **Where members of the public/patients are involved, they must be compensated for their time and contributions; this should be reflected in the project budget.**

If **No**
Please explain why PPI is not applicable to your project.

The word limit is **600 words.**

4.7 Project Description Support

*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. They must not be embedded within the text of the Project Description. The maximum size is 2MB.*

4.8 Project References

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

For peer-review 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[16]:

Authors, year, article title, journal, publisher, DOI
Author(s), year, dataset title, data repository or archive, version, global persistence identifier

4.9 Additional information on the research

4.9.1 Potential risks and ethical concerns

Please address any potential risk and/or harm to the safety of the patients or human subjects/participants in the study, 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. The word limit is **400 words.**

4.9.2 Gender 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 between women and men in all research activities. Please identify and explain how you address gender issues in your research.

Indicate whether a potential gender dimension may be present or could arise in the course of your proposed research:

- If so, outline how gender analysis will be integrated in the design, implementation, evaluation, interpretation and dissemination of the results of the research proposal.
- If not, outline why it is not relevant to the research proposal.

The word limit is **500 words.**

4.9.3 Arrangements for sample collection for biobanking

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

[16] Please refer to FORCE 11 principles for further information **https://www.force11.org/group/joint-declaration-data-citation-principles-final**

If Yes, 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, describing data protection measures where appropriate. Please reference the 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]. The word limit is **400 words.**

4.9.4 Compliance with Data Protection Regulations

Please comment on how your study complies with national and/or EU Data Protection Regulations, if relevant, especially where the study involves the transfer of data outside of the EU. The word limit is **300 words.**

4.9.5 IP considerations

The Lead Applicant together with the Host Institution 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[4]. 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 **500 words**

5. Research & Professional Development Plan

5.1 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*

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

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.

5.2 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.*

5.3 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.

5.3.1 Travel Grant: Sponsor Contact Details

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

5.3.2 Travel Grant: Overall Plan

Within the overall plan, agreed with your mentor and employer, if applicable (for part-time Lead Applicants), you are asked to describe where and when you are planning to avail of the *Travel Grant* and to provide details of to whom you will travel, including 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 describe 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 his/her 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.*

6. Institutional and Infrastructural Support

6.1 Host Institution and other support

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

6.2 Access to clinical research infrastructure

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
- Information on the costs of providing the service/input, setting out where this is provided in-kind, from additional funding or requested from the project budget
- Any issues related to feasibility

The word limit is **600 words.**

Applications involving patients that 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.

7. Project Budget

Please provide a summary and justification of the costs and duration associated with the project.
There is no set limit per annum therefore the proposed budget per annum should reflect anticipated annual costs.

The budget requested and award duration must reflect the scale and nature of the proposed research and reviewers will thoroughly assess the level of funding and timeframe requested when reviewing the proposal.
A **full detailed breakdown** of **costings** and **justification for all funding** is required for items listed under each subheading. You are strongly advised to seek guidance from the research office/finance office in the host

institution before completing this section of the form. ***The HRB will not provide additional funding in the case of either under-estimates or over expenditure.***

- **Salary-related costs** for 50% FTE of the salary-related costs of the Lead Applicant. The HRB funding will cover the corresponding FTE of the salary-related costs of the locum replacement of the lead applicant in line with the appropriate scale;
- Research-related costs at a maximum value of 50K during 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

Please state your current salary and the relevant salary scale and point. If available, please provide the link to the scale.

Funds will be provided for the following:

1. **Personnel costs**	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	**Lead Applicant's salary** Gross Annual Salaries (including 5% employee pension contribution) negotiated and agreed with host institution. Applicants are advised that public sector pay increases valid from 01 Sept 2019 and 01 Oct 2020 have been published. Please apply a salary contingency of 2.5% p.a. from 01 Oct 2021. **Note:** The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators.
b) Employer's PRSI	Employer's PRSI contribution is currently calculated at 10.95% of gross salary. This will rise to 11.05% on 01 Jan 2020.
c) Employer Pension Contribution	Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution.

	If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
2. **Running Costs**	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, 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 involving members of the public or patients in your research e.g. consultation workshops, costs of participation in advisory groups, travel expenses, training in public and patient involvement in research, etc. should be charged to running costs. The following costs are ineligible and will not be funded: inflationary increases and cost of electronic journals.
3. **Equipment**	**At a maximum value of €2K**: Funding for suitably justified small items of equipment can be requested when properly justified. Personal/Stand-alone computers <u>will not</u> be funded as these are considered a standard piece of office equipment. Dedicated laptops or similar equipment that is required specifically for the project due to the nature of the research, will be considered where appropriately justified. All costs must be inclusive of VAT, where applicable.
4. Training costs	In line with the Research and Professional Development Plan submitted, you are asked to list the costs of training and development over the lifetime of the award. This can

	include costs associated with acquiring 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. Please refer to the HRB policy on Open Access to Published Research[18]. **Publications:** Typically, the average HRB contribution towards publication costs is €1,750/per article or free of charge through the **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**). **Conferences:** We envisage that conference costs will be typically around €500/year per researcher for national conferences and €1,500/year per researcher for international conferences. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary).
6. FAIR Data Management Costs	Costs related to data management, FAIRification, storage and archiving of research data in line with best practice of data management and stewardship and the FAIR principles **incurred during the lifetime of the project** should be included. Please consult Appendix IV of the Guidance Notes for examples of eligible costs.
7.Travel Grant/Research Experience Abroad	A contribution 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. 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.

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

Note: *Applicants should allow sufficient time to obtain ethical approval as a copy of any of these approvals must be submitted to the HRB before the start of the award. It is suggested that these are sought in parallel with submission of an application to the HRB. If the ethical approval has already been secured for this* ***application*** *you* ***may*** *upload a copy of the relevant approval letter.*

9. Other Funding Sources

9.1 Please indicate if you have submitted a similar application to the HRB or another funding body previously or currently. If this application has been submitted elsewhere, please indicate which scheme or funding body, project title, result of submission or when outcome is expected and the amount of award. The word limit is **200 words.**

9.2 Provide details of any other financial support available for this or any other related project - e.g. if you project is linked to or dependant on existing national or international studies. Indicate project title, funding agency or sponsor and the amount of award. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review. The word limit is **500 words.**

10. Supporting Documentation

The following documents must be uploaded to complete the application:

Mandatory documents:

1. Letter of Support to Lead Applicant from the current clinical employer;
2. Objectives and Deliverables Gantt Chart;
3. 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;
- SWAT: Host Trial Full Protocol
- SWAT: PI support letter;
- Copy of Ethical Approval.

Submission of Applications

The deadline for submission of complete applications is 07 November 2019 at 13:00.

1. After successful validation the Lead Applicant may submit the application. It will then be routed to the designated signatory at the Host Institution for their approval.
2. If a signatory rejects the application the Lead Applicant 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 Host Institution 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 Host Institution's Letters of Support, Collaborator Agreement Form, Gantt charts etc. It is the responsibility of the Lead

Applicant 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.

Appendix III: Resources/Useful Links

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

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/SUPPORTS

Health Research Board Clinical Research Facility, Cork
http://www.ucc.ie/en/crfc/

Health Research Board Clinical Research Facility, Galway
http://www.nuigalway.ie/hrb_crfg/

Wellcome Trust-Health Research Board Clinical Research Facility, St James's Hospital
http://www.sjhcrf.ie/

Clinical Research Centre, Royal College of Surgeons in Ireland
http://www.rcsicrc.ie/

Clinical Research Facility, University College Dublin
http://www.ucd.ie/medicine/ourresearch/researchenvironment/ucdclinicalresearchcentre/

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

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

OECD Guidelines on Human Biobanks and Genetic Research Databases
http://www.oecd.org/sti/biotech/guidelinesforhumanbiobanksandgeneticresearchdatabaseshbgrds.htm

ISBER Best Practices for Repositories
http://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)
http://biospecimens.cancer.gov/practices/

RESEARCH PRIORITIES & PUBLIC INVOLVEMENT IN RESEARCH

INVOLVE UK website for resources on Public and Patient Involvement in research
http://www.invo.org.uk

Patient-Centred Outcomes Research Institute (PCORI)
http://www.pcori.org

Public Involvement Impact Assessment Framework (Provides tools to maximise impacts of involving members of the public in their research in individual projects)
http://piiaf.org.uk/

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
http://www.lindalliance.org/Patient_Clinician_Partnerships.asp

Campus Engage
http://www.campusengage.ie/what-we-do/publications/

GENDER 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

DATA MANAGEMENT AND SHARING and FAIR principles

Supporting the International Alignment of Research Data Management – Science Europe
https://www.scienceeurope.org/supporting-the-international-alignment-of-research-data-management/

FAIR data principles FORCE 11
https://www.force11.org/fairprinciples

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

Digital Curation Centre: Data management plans
http://www.dcc.ac.uk/resources/data-management-plans

Data Stewardship Wizard
https://dmp.fairdata.solutions/

Research Data Management Starter Kit
https://www.go-fair.org/resources/rdm-starter-kit/

Registry of Research Data Repositories
http://www.re3data.org/

Zenodo Data Repository (OpenAIR)
https://zenodo.org/about
https://zenodo.org/

Appendix IV - HRB Data Management Plan costing

For researchers, the move to FAIR and open[19] data, where possible, means that they have the responsibility to think about what data their research will produce, how these data will be described, and how they can be made available in such a way so as to benefit science and society in general. This means that they have to draw up a data management plan (in collaboration with professionally trained colleagues) and find suitable data repositories at a very early stage of their research. FAIR principles should be applied to all research involving data and/or software creation and so be included in all data management plans. The DMP is not be a goal in itself and should not be regarded as an additional administrative hurdle. It should instead provide an opportunity at an early stage of the research project to consider how the data generated within a project will be stored, managed and safeguarded, and thus be part of the research process from the outset. As a project progresses, the data generated may well change in type and volume, so the DMP should be seen as a dynamic framework which should be maintained and modified as the research advances.

Lead Applicants from the following institutions (DCU, NUIG, UCC, UCD, UL, RCSI and TCD), where data steward professionals have recently been trained, will participate in a pilot the HRB is conducting on the implementation of data management and stewardship plans in HRB awards from two schemes (ILP 2019 and Emerging Investigator Awards 2019).

In the budget section Lead Applicants from the above HIs are required to add any costs associated to the management of their data during the project and data FAIRification (see budget section).

The preparation of a DMP is still not a requirement of this funding scheme. However please refer to the HRB data policy which will come into effect in January 2020. It is still recommended that Lead Applicants prepare a DMP with the support of data managers and stewards in the host institution once the award is made. Lead Applicant have the opportunity during the preparation of the application to budget for it.

Guidance on the Budget section for the FAIR DMP

FAIR Data Management Costs (applicable to Lead Applicants from institutions participating to the HRB Pilot): Costs related to management, FAIRification, storage and archiving of research data (as part of the DMP pilot the HRB is currently conducting) in line with best practice of data management and stewardship and the FAIR principles. Some of the eligible costs may include:

- staff time per hourly rate for e.g. data collection, data anonymisation, cleaning, preparing data for publication, unless these are significant costs in which case the staff member should be added under salaried personnel;

[19] *Please note that not all FAIR data are necessarily open. Where data raises data protection or security concerns, controls and limits on data access will be required. In some cases, it will be appropriate for researchers to delay or limit access to data to secure intellectual property protection. Any such restrictions on access should be justified, made explicit via machine-actionable licensing and built-in accessibility protocols mechanisms.*

- staff time per hourly rate for data stewardship, e.g. preparing and writing the DMP, keeping the document up to date during the award, unless these are significant costs in which case the staff member should be added under salaried personnel;
- costs to access a secondary dataset;
- FAIRification of data produced or data reused during the project which could be done by a third party service provider e.g. defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing FAIRified data and relevant metadata, deposit in relevant repository;
- Costs to make data open and/or to share data, e.g. data anonymisation, costs for depositing research data in an open access data repository;
- Others, please explain further

Please note: The HRB is currently not covering the cost of long-term preservation of data.
Please note this list is not exhaustive and aims to provide examples only of eligible costs.