HRB Applying Research into Policy & Practice Post-doctoral Fellowships 2018: Pre-Call Announcement

Update 17 October 2017

The call launch has been deferred to 8 January 2018.

The overarching aim of the 'Applying Research into Policy & Practice Postdoctoral Fellowship (ARPP)' scheme is to accelerate and enhance the development of talented and skilled health researchers at mid-stage of their research career through a mentored post-doctoral period in a cross-disciplinary and/or cross-sectoral environment. Ultimately, we want to build the capability and leadership potential of talented researchers who can apply and transfer research evidence into improved healthcare and health policy, lessening the gap between research findings, health policy and clinical practice.

The scheme offers two different arms for
1) In-practice healthcare and health policy professionals and
2) Academic researchers, in recognition of the two main career gaps identified and the different structures required to support them.

It is envisaged that the HRB will award up to 40 fellowships during the strategy with an overall investment of €9m.

The guidance notes to the scheme and guidelines for completing the application are below. Small changes before the launch may apply in the application form.
Please contact the HRB if you have queries regarding eligibility.

What is the timeline for applications to the first call?

Call Opening: 08 January 2018
Call Closing: 15 March 2018

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HEALTH RESEARCH BOARD

Applying Research into Policy & Practice Postdoctoral Fellowships (ARPP) 2018

Building the capability and leadership potential in applied health research

Guidance Notes

Key Dates & Times	
Applications Open	**08 January 2018**
Application Closing Date	**15 March 2018, @ 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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GUIDANCE NOTES

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1. Overview

The overarching aim of the 'Applying Research into Policy & Practice Postdoctoral Fellowship (ARPP)' scheme is to develop talented and skilled health researchers at mid-stage of their research career. It particularly emphasises the ability of applying research evidence into improved healthcare and health policy, lessening the gap between research findings, health policy and clinical practice. The scheme will support the conduct of applied health research studies through individual fellowships. It provides a mentored post-doctoral period in a cross-sectoral and preferentially cross-disciplinary environment.

This new scheme will complement secondary capacity building supporting postdoctoral researchers through project, programme or team-based awards. The ARPP scheme will replace the Interdisciplinary Capacity Enhancement Awards (ICE).

Two main career gaps were identified, which require different structures to support them. Therefore the scheme offers two different arms for 1) in-practice healthcare and health policy professionals and 2) academic researchers. It is envisaged that the HRB will invest up to €9m on this initiative during the overall strategy.

The figure below summarises the key characteristics of the two different arms of the fellowship scheme.

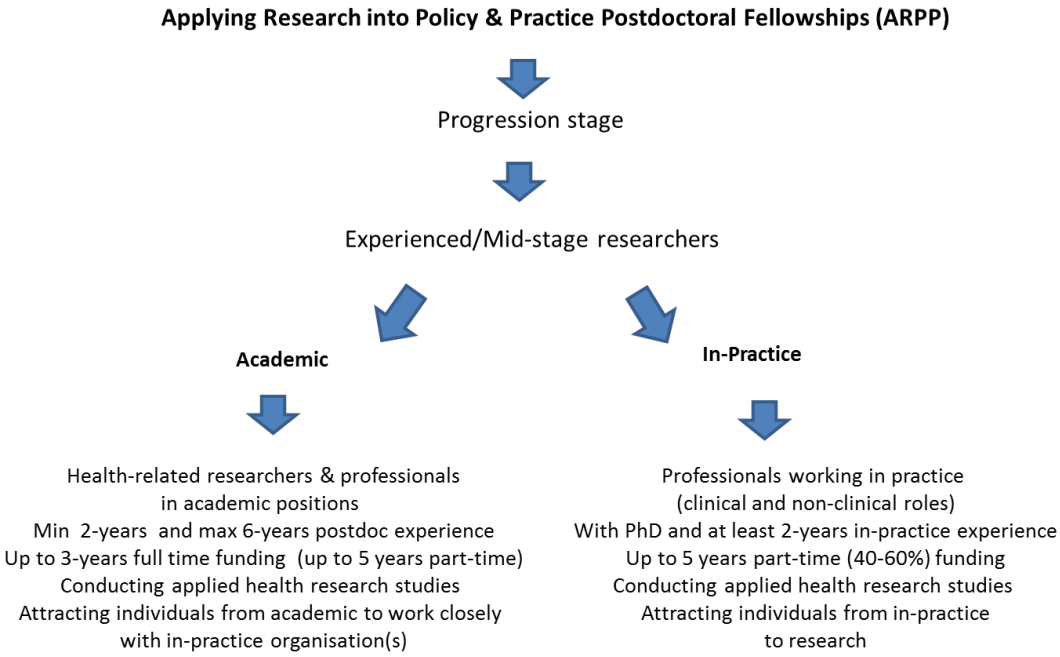

Figure 1: Diagram summarising the key characteristics of the two different arms of the ARP fellowship scheme.

2. Introduction

The HRB has identified training, career development and support of exceptional researchers, talent and leadership as a key enabler (Enabler A) of *Research. Evidence. Action.* In order to implement a coherent programme of activities, a framework and action plan to support Health Research Careers was developed [1]. It describes the HRB's vision and guiding principles in this area, and a coherent model for a research career path along with the actions needed to effectively develop and deliver training, support and career development between now and 2020. Overall, this will contribute to the development of a skilled workforce engaged in health research in Ireland.

In the current Strategy the HRB states it intention to continue supporting mid-stage researchers[2] during the consolidation and progression phase. The most significant workforce and capacity gaps at mid-career stage across the HRB strategic portfolio were identified as follows:

1. *Individuals who are currently working in the management or delivery of health and social care services (also referred as professionals[3]), who have completed a PhD (or equivalent) and struggle to find further opportunities to advance their research activities/career* - These individuals will need protected research

[1] **http://www.hrb.ie/index.php?id=1049**

[2] An **experienced or mid stage researcher** is a PhD holder or equivalent during consolidation and progression phases who aims to increase the breadth of his/her research knowledge, skills, methodologies and capabilities as well as establishing strong cross-border collaborations and networks. Some researchers at this stage might aim to transition towards becoming independent researchers.

[3] **Professionals** are individuals in health-related professions or roles who are generally involved in health service delivery, organisational activities, health policy or financing. They include clinicians and other healthcare professionals, healthcare personnel, health system personnel, health policy-makers and others.

time while remaining within the services. By supporting in-practice professionals during this stage of their research career we aim to provide a coherent research pathway from doctoral training towards leadership stages. It will ultimately foster a research culture within our health and social care services and ensure that research is conducted and led by well-trained researchers therein. This fellowship is about enabling these individuals to remain in practice while at the same time conducting research relevant to their practice roles and the health environment where they are currently working.

2. *Academic researchers particularly during their progression stage (e.g. at least 24-months postdoc experience)* – The direct support of academic mid-stage researchers will address a long-standing gap in the HRB's career portfolio. We think is timely to support researchers with the skills and expertise to drive research informed by and impacting on policy and practice. Ultimately, it will provide a new generation of academic researchers for the succession management in our academic institutions and can also make a difference in practice (primarily in this context non-clinical), in service or in policy roles into the future.

We will address these two gaps through the **Applying Research into Policy & Practice Post-doctoral Fellowship (ARPP) scheme**.

In line with this strategic objective, the HRB is now inviting applications for its 2018 Applied Research into Policy and Practice Postdoctoral Fellowships (ARPP).

3. Aims and objectives

The **overarching aim** of the (ARPP) scheme is to develop talented and skilled health researchers at mid-stage of their research career. It particularly emphasises the ability of applying research evidence into improved healthcare and health policy, lessening the gap between research findings, health policy and clinical practice.

The **main objectives** are

1. To support capability of academics and in-practice professionals in applied health research at postdoctoral level and particularly during their progression stage;
2. To support researchers who have the potential to establish themselves as future independent researchers and potential leaders in applied health research;
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 application and transfer of research findings into policy and/or practice;
4. To provide direct experience for ARPP Fellows in the conduct of health research projects that lessen the gap between research findings, clinical practice and/or heath policy, and which ultimately impact on health outcomes.

It is expected that fellows will:

- Strengthen their research experience
- Broaden their horizons

- Learn new research skills and methodologies
- Establish new collaborations and partnerships
- Develop independent thinking more clearly
- Manage an award on their own right.

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

Note: HRB Fellowships are personal research training fellowships and are not intended merely as a means to fund a research project. A combination of the proposed project **and** a good training plan in a strong research training environment will provide the lead applicant with the most valuable experience during their fellowship. To that end applicants are required to provide a detailed personal training and development plan, which has been agreed with their mentor. This plan should include:

- Formal and informal training for career development
- Research training skills/techniques specific to the project
- Generic research training skills such as data handling/protection
- Methodological/experimental design
- Statistics
- Dissemination and knowledge sharing
- Consideration of intellectual property issues
- Ethical issues.

The development of transferable skills such as good oral and written communication/presentation, IT and time- and resource-management skills is also expected. *Applications which do not contain a convincing training and development plan are typically not very competitive.*

4. Scope

The call focuses on **applied health research** in areas of strategic importance at local, national or international level (as opposed to fully investigator-led research). The case for the selection of a particular research topic will need to be justified by demonstrating a need (e.g. reference to the recent Oireachtas Committee report on the Future of Health Care[4], strategies for specific disease or policy areas etc.) and by 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[5] as defined in the Framework for the Health Research Careers). Research projects should have the objective of uncovering and/or identifying of

[4] **http://www.oireachtas.ie/parliament/mediazone/pressreleases/2017/name-42326-en.html**

[5] **Innovators** are 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. **http://www.hrb.ie/health-research-careers/**

findings which can impact on policy and/or practice. Lead Applicants are welcomed to propose research projects related to other ongoing research studies within the scope of this call.

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

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.

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.

This scheme will not fund:

- Applications involving basic biomedical research;
- Applications using cell lines, animals or their tissue including pre-clinical models
- Stand-alone systematic reviews;
- Applications seeking to evaluate all phases of an intervention
- Applications that aim to conduct a full-scale definitive intervention/trial;
- 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 from individuals applying for, holding, or employed under a research grant from the Tobacco industry;
- Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Note: Please note feasibility studies[6] conducted in preparation for a future definitive intervention are eligible under the ARPP scheme.

[6] ***Sandra M. Eldridge et al. Defining Feasibility and Pilot studies in preparation for Randomised Controlled Trials: Development of a conceptual Framework****. PLoS ONE 11(3): e0150205*

5. Details of the Fellowship arms, eligibility and funding

In recognition of the two main career gaps identified and the different structures required to support them, the scheme will have **two different arms**:

A) In-practice (ARPP-P)

The **'In-practice' arm** of the fellowship scheme is open to individuals who are currently working in the management or delivery of health and social care services in the Irish health. This scheme is about enabling fellows to remain in service while at the same time conducting research. It will provide protected and mentored research time (40-60% FTE) for up to five years. Lead Applicants must demonstrate ownership of the research project, some research vision, collaborative approaches and the potential to becoming future leaders in applied health research. Research studies should address questions relevant and responsive to the environment the fellows are working in. Additionally, research studies should have high potential to bridge the gap between the acquisition of new knowledge from research and its application in policy and practice at a local, national or international level.

Ultimately, we want to foster a culture of research within our health and social care services and a high quality, well trained cadre of individuals therein.

Eligibility of Lead Applicants (ARPP-P)

For the purpose of this scheme Lead Applicants who are **in-practice professionals** with appropriate research experience may apply:

Professionals *are individuals engaged in different health-related professions or roles, such as clinicians and other health care professionals, healthcare personnel, health system personnel, health policy makers and others, who are generally involved in planning and/or delivering healthcare services and/or engaged in healthcare policy.*

Lead applicants **must**

- be mid-stage/experienced researchers[7] and have a PhD or equivalent;
- be currently employed in a practice-based role with a public, private or not-for-profit health-related organisation/agency currently delivering or organising healthcare, including applicants who are self-employed practitioners in private practice, and continue the in-practice role during the non-fellowship time;
- be able to demonstrate at least two years relevant experience pre or post PhD (or equivalent) in their professional role in a health-related organisation/agency prior the deadline for applications (15 March 2018).;

[7] *An **experienced or mid stage researcher** is a PhD holder or equivalent during consolidation and progression phases who aims to increase the breadth of his/her research knowledge, skills, methodologies and capabilities as well as establishing strong cross-border collaborations and networks. Some researchers at this stage might aim to transition towards becoming independent researchers.*

- ❖ be able to demonstrate some contributions to scientific knowledge. This contribution may be in a variety of formats such as peer-reviewed articles, published 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;
- ❖ be able to devote at least 40% and max 60% of their time to research and to this end have a written commitment from their employer to protect this research time;
- ❖ be able to provide proof of eligibility to practice if from the health and social care professions**.**

The Lead Applicant 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.

Note: *Active research or professional experience will be considered when assessing the Lead Applicants track record for eligibility purposes. Career breaks, flexible working arrangements**,** changes in sector (e.g. industry, health organisation/agency) will be taken into account when assessing the research and/or professionals experience.*

Note: *Equivalent period to PhD is at least four years active research experience post-primary degree. Please call the office to confirm your eligibility.*

In addition, the Lead Applicant must:

- Be an EU citizen or, if from outside the EU, have permanent Irish resident status or a valid work permit;
- Provide evidence of appropriate mentoring arrangements.
- Identify a suitable Host Institution for their fellowship. Please note that the HRB Host Institution Policy and a list of approved Host Institutions is available at **http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/.**

Note: *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 peer-review. Candidates will be informed accordingly.*

Note: ***Each Lead Applicant may only submit one application to this fellowship scheme this year.***

Funding and Duration (ARPP-P)

Each ARPP-P award will have a maximum of five year support.

Funding will support:

- Salary and related costs pro rata at minimum value 40% and maximum value 60% of Level 3 point 4 of the most recent IUA scale. Salary levels for successful fellows must be also justified by the experience of each individual to date and the current salary.
- Research running costs up to €30,000 (in exceptional cases where the specific nature of the research methodology proposed is particularly expensive, an additional supplement up to €10,000 can be requested for running costs, if suitably justified;
- Small equipment costs up to €2,000
- Dissemination and knowledge exchange costs up to €3,000
- Training and Development allowance up to €3,000
- Research Experience Abroad up to €6,500

B) Academic (ARPP-A)

The **'Academic' arm** of the fellowship will support health-related researchers, including healthcare professionals, who are typically in academic positions. It supports R2-mid-stage researchers during the progression stage of the research career. Lead Applicants must demonstrate ownership of the research project, some research vision, collaborative approaches and the potential to becoming future leaders in applied health research. The scheme is not suitable for researchers immediately after or shortly after completing the PhD degree or equivalent (during consolidation stage). Please note that other HRB indirect funding schemes (e.g. ILP, EIA, APA and others) support early stage postdocs and the next Emerging Investigator Awards for Health, targeting researchers ready to transition to independence, will be launch in mid-2018.

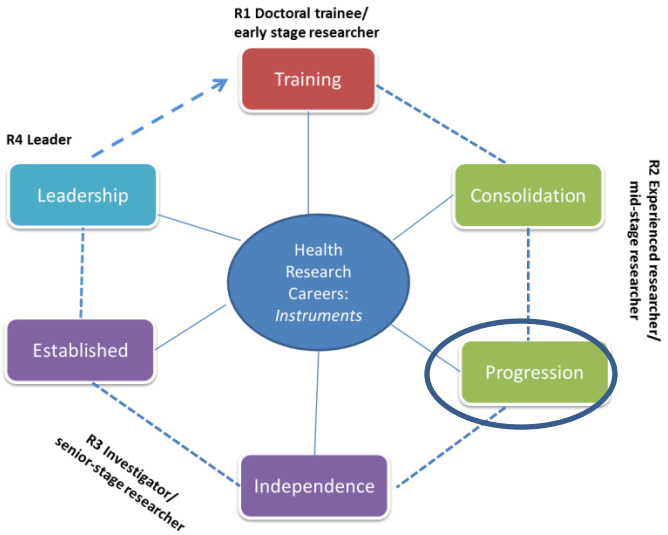

Figure 1 - The HRB Health Research Career Path

The fellowship will support individuals typically for up to three years full time in the conduct of research projects in areas of local, national or international strategic importance (as opposed to fully investigator-led research)

with potential to reduce the gap between research findings and health policy and clinical practice. Part-time arrangements can be requested with duration up to five years.

Given the applied aspect of the fellowship scheme fellows are encouraged to closely collaborate with health-related organisations/agencies (e.g. delivering health, managing healthcare , decision or policy makers, other knowledge users, charities, etc.) in Ireland and/or internationally. Whilst in-practice fellows will spend time in an academic environment, academic fellows are strongly encouraged to spend time in a setting delivering and/or managing health care (e.g. the HSE and any HSE setting, voluntary hospitals, charities, Department of Health, or others as relevant). The mentor will be crucial in guiding the applicant in this. We want to encourage these collaborations in order to inform the research regarding the realities of current policy and clinical practice, and to increase the applicability and transferability of the research findings into policy and clinical practice. This will provide experiential learning to the fellows (e.g. learning how health-related organisations delivering and/or organising healthcare work).

Eligibility of Lead Applicants (ARPP-A)

For the purpose of this arm of the scheme, Lead Applicants who are health-related researchers, including healthcare professionals not in-practice, with appropriate research experience may apply.
Health-related researchers *are individuals who are usually engaged in health-related research activities mainly in academic or other research institutions.*

The Academic arm of the scheme is also open to the following groups of individuals who have the support of a HRB approved Host Institution in Ireland and a mentor.

- Individuals currently working in areas outside health with an interest of moving into applied health research;
- Individuals not currently working in Ireland;
- Individuals currently in career break or working outside the academic setting.

A Lead Applicant must

- ❖ Be mid-stage/experienced researchers[8] and have a PhD or equivalent
- ❖ Have a minimum of two years and maximum of six years[9] active postdoctoral experience prior to the submission of an application (15 March 2018).
- ❖ Be able to demonstrate some contributions to scientific knowledge. This contribution may be in a variety of formats such as peer-reviewed articles, published 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.

[8] An **experienced or mid stage researcher** is a PhD holder or equivalent during consolidation and progression phases who aims to increase the breadth of his/her research knowledge, skills, methodologies and capabilities as well as establishing strong cross-border collaborations and networks. Some researchers at this stage might aim to transition towards becoming independent researchers.

[9] Please note that for more experience postdoctoral researchers the next Emerging Investigator Awards for Health call will be launched in mid-2018

The Lead Applicant 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.

Note: *For healthcare professionals or other prospective applicants in faculty positions please note that the award will not buy research time.*

Note: *Active research or professional experience will be considered when assessing the Lead Applicants track record for eligibility purposes. Career breaks, flexible working arrangements, changes in sector (e.g. industry, health organisation/agency) will be taken into account when assessing the research and/or professionals experience.*

Note: *Equivalent period to PhD is at least four years active research experience post-primary degree. Please call the office to confirm your eligibility.*

In addition, the Lead Applicant must:

- Be an EU citizen or, if from outside the EU, have permanent Irish resident status or a valid work permit;
- Provide evidence of appropriate mentoring arrangements;
- Identify a suitable Host Institution for their fellowship. Please note that **the HRB Host Institution Policy** and a list of approved Host Institutions is available at **http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/** .

Note: *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. Candidates will be informed accordingly.*

Note: *Each Lead Applicant may only submit one application to this fellowship scheme this year.*

Funding and duration (ARPP-A)

Each award will have a maximum of three year full time support or up to five years part-time (minimum 40% and maximum 60%).

Funding will support:

- Salary and related costs full time or pro rata at maximum value of Level 2 point 10 of the most recent IUA scale. The salary must be properly justified by the research experience of the individual to date and the current salary.

- Research running costs up to €30,000 (In exceptional cases where the specific nature of the research methodology proposed is particularly expensive, an additional supplement up to €10,000 can be requested for running costs, if suitably justified);
- Small equipment costs up to €2,000
- Dissemination and knowledge exchange costs up to €3,000
- Training and Development allowance up to €3,000
- Research Experience Abroad up to €6,500

5. The research team and other support

The application should have **inter-sectoral** and/or **cross-disciplinary**[10] 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.

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 for the fellow to progress through the research career 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 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.

Collaborators

An official Collaborator is an individual or an organisation that provides an integral and discrete contribution (direct or indirect) to the proposed research activities. A collaborator may supply material, provide training,

[10] 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).

provide access to specific equipment or groups, specialist staff time, trials advice or other support, access to data and/or patients, instruments or protocols or may act in an advisory capacity. They can be based in an academic institution, a private enterprise, a healthcare organisation or agency, or come from the charity sector.

Profile details must be provided for ALL official collaborators. The terms of any collaboration should be determined early and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up collaboration agreements.
Up to **10 Research Collaborators** can be included.

Relevant gatekeepers should be named as Collaborators within your application form if the success of a project is dependent on access to

- Healthy volunteers or patients
- Vulnerable population groups
- Data or databases
- Existing national or international study (e.g. an existing cohort or longitudinal study or a clinical trial)

If the study is part of a clinical trial, it is advised that you include the full protocol where available. This will greatly assist the peer-reviewers and panel members to assess the application. Applicants proposing a trial of any design are advised to avail of methodology support/advice/services from facilities such as the HRB-Trial Methodology Research Network and/or the Clinical Research Facilities.

Each official collaborator must complete a **Collaboration Agreement Form.** A template Collaboration Agreement form will be made available on GEMS for download and this must be completed and include the following.

- Details setting out the nature of the collaboration and how the Collaborator will be involved in the proposed research and add value to the project;
- Confirmation of Collaborator's commitment to the proposed project;
- Details setting out the value, relevance and possible benefits of the proposed work to the Collaborator;
- Details setting out the period of input/support;
- Detail how the results of this collaboration will be disseminated;
- Details of the costs requested (where relevant) with appropriate justifications.

The terms of any collaboration should be determined early and relevant agreements should be in place by the onset of the project. The HRB advises that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up collaboration agreements.

Public and Patient Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public in the research that we fund. This 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. PPI is research carried out '**with'** or '**by'** members of the

public rather than '**to'**, '**about'** or '**for'** them. It is distinct from and additional to activities which raise awareness, share knowledge and create a dialogue with the public and it is also distinct from recruitment of patients/members of the public as participants in research.

PPI represents an active partnership between members of the public and 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 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 to 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 public involvement is likely to vary depending on the context of each study.

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 the advice, trial and 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).

Applicants need to provide an **Infrastructure Agreement Form** (including national and international infrastructures as required). The form set out

- The nature and scope of the service or collaboration
- The rationale behind the choice of infrastructure and
- Any costs associated with the project (including those provided as in-kind contributions).

Applications which do not seek the advice and/or support from existing research infrastructure will be asked to justify why they have not done so.

6. 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 **15 March 2018**.

  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. Following an initial eligibility check, eligible applications are sent to international peer-reviewers for assessment and short-listing. Short-listed candidates will be invited to attend for interview by an international Interview Panel whose task is to make final funding recommendations to the Board of the HRB. To ensure the integrity of the assessment process, conflict of interest and confidentiality are applied rigorously in each stage of the process. To ensure gender balance in decision-making, the HRB aims to reach the international best practice target of 40% of the under-represented sex in all HRB panels where possible. Gender will also be considered when appointing the position of Panel Chair.

The scheme will use a two phase assessment process. In accordance with this process all eligible applications will be evaluated as follows:

Phase 1 – International Peer Reviewers

For each eligible application the HRB aims to receive written feedback from at least three international peer reviewers. The individual scores for each proposal are averaged by the HRB. Highest ranked applicants will be short-listed with the guidance of the international panel and invited to attend an interview with the Interview Panel. Feedback from the peer-reviewers will be provided so that the candidates can address specific comments during the interview. The peer reviewer's comments do not include the scores or the identity of the peer reviewers. Approximately a three to four-week notice is given to the short-listed candidates.

Phase 2 – International Interview Panel

The next stage of assessment involves convening one international Interview Panel per each arm comprising of six to eight members and an independent Chair. Panel member are selected based on the range of applications received and the expertise needed (e.g. research area and methodological and analytical approaches, coaching and mentoring, knowledge translation/applied health research, etc.).

The interview will begin with a short PowerPoint presentation of the research proposal, career and research vision followed by questioning by the Interview Panel members. Panel members are assigned as lead and secondary interviewers to specific applications.

At the end of each Panel meeting, a final score is collectively agreed for each candidate and then ranked according to score. HRB staff members are present at this meeting to ensure procedural consistency between panels and to take notes for the feedback process. If it is not possible to differentiate between applications around the funding cut off based on the assessment criteria, the HRB gender policy[11] includes gender balance in the leadership of the research team as a factor which may be used to rank proposals with the same scores.

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 applicants to notify them of the outcome. It is estimated that from the deadline of the call to the HRB decision after the assessment will take five-six months.

The reviewers will evaluate 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**.

1. **Standing and potential of the Lead Applicant;**
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.**

Note: The HRB are currently planning a public review process for this scheme to provide specific feedback to applicants *on the quality of their PPI plans. This feedback will be independent of the peer review process and will* ***not be shared with the panel****. However, panel members might take PPI approaches into consideration under any of the assessment criteria.*

[11] http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/gender-policy/

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.

7. Timeline

Key Dates	
08 January 2018	Call opening
15 March 2018	Call closing for applications
End March 2018	Eligibility completed
April - June 2018	Peer-review
July-Mid-August 2018	Panel review and shortlisting – Applicants informed
Early September	Panel interview meetings
28 September 2018	Board Approval
October – November 2018	Budget negotiation and contracts
01 December onwards 2018	Start of awards

8. Contacts

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The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's 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: 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 'Manage My Details' section of GEMS.
- Lead Applicants previously registered on GEMS can login to GEMS and update any information regarding their contact and CV details in 'Manage my details'.

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

Once the Lead Applicant selects the application remit on GEMS, s/he will be asked to go through a check list of mandatory Yes/No questions. In order to start the application the Lead Applicant must satisfy the conditions of this check list.

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

1. 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[12].

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.

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

2. 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.

3. Project Details

3.1 Project Title

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

3.2 Which arm are you applying for?

- Academic
- In-practice

3.3 Project Duration and Start date

Please indicate the expected length of the proposed project in months (max 36 months for full-time and 60 months for part-time) and the proposed start date. The earliest start date is 01 December 2018.

When selected part-time (all Lead Applicants In-practice arm and in Academic arm, if applicable) you must indicate the percentage of time to be dedicated to the research project.

3.4 Letter of support for part-time arrangements

- ARPP-P Lead Applicants must also provide a letter of support on headed paper to this application from the manager/director/CEO of the in-practice organisation where currently working demonstrating their support for the research protected time and part-time arrangement proposed within this research fellowship. For successful ARPP-P Lead Applicants, the current non-academic employer will be required to sign a declaration as part of the award contract.
- ARPP-A Lead Applicants applying for part-time and combining with other academic-related activities must also provide a letter of support on headed paper from the Head of Department/School or equivalent person at the Host Institution where currently employed.

3.5 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 regards to the variety of research funded by the HRB and may be posted on the HRB website. The word limit is **300 words**.

3.6 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**.

3.7 Keywords

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

4. 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 details** are managed in 'manage my details' section of GEMS and are automatically included in any application created involving that individual.

4.1 Gender (M, F or other)

4.2 Type of Researcher

Please describe yourself as:

- ✓ Professional in-practice
- ✓ Health-related researcher
- ✓ Health and Social care Professional Academic
- ✓ Other, please specify

4.3 Personal Declaration

Please describe (1) why you are well suited for this fellowship, (2) how this fellowship will further progress your research vision and career trajectory and (3) how your research experience and professional skills to date will help you to achieve the main objectives of this call. The word limit is **600 words**.

If you wish to explain impediments 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.

You must reference up to four of your most relevant career contributions/research outputs (not just restricted to peer-review publications and may include contributions to health policy or practice, or to technology or product discovery and development) that specifically highlight your experience and expertise most suitable for this funding application. Please list your research outputs manually in the box provided.

4.4 Contribution to scientific knowledge and Research Outputs

Please detail your four most relevant contributions to scientific knowledge, relative to your career's stage and the years of active research experience. You should briefly indicate

- Brief title of the topic/project
- Background of the idea and scientific question;
- Main findings from the research;
- Influence and/or application and/or impact of the findings to health and/or other research field;
- Lead Applicant's specific role in the research project intellectually conceiving or conducting the research, supervising staff, writing the paper)

The word limit is **400 words** for each contribution described

For each contribution listed, you should reference at the end of each paragraph up to two of your research outputs that are relevant to the described contribution (such as peer-reviewed articles, research data and datasets, research material, databases, nanopublication[13], 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) Please also state if any of these research outputs were made openly available.
For original research publications please provide the PubMed Central ID (PMCID) reference for each of these.

4.3 Total number of peer-review publications

Please provide the total number of publications which you have authored and/or co-authored.

5. The Research Team

5.1 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 for the fellow to progress through the 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

[13] A nanopublication is the smallest unit of publishable information: an assertion about anything that can be uniquely identified and attributed to its author **http://nanopub.org/wordpress/**

the Lead Applicant to participate in the application as Mentor. Registered Mentor can decide whether to accept or reject their participation. If the proposed mentor rejects participation in an application, the Lead Applicant is informed and may revise the application accordingly. The Mentor who accepts will be able to complete some section of the application and also edit the application. *The system will flag if another user is working on the application form at the same time via a pop-up warning. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data but it is advisable that they contact the other person directly to avoid losing data when applying the override function.*

Prior to validation and submitting the application to the authorised signatory of the nominated 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 **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) and Publication Record will asked in the application form so it is not essential to fill this part here.

5.12.1 Please describe yourself as:

- ✓ Health and social care professional with a joint or full academic appointment
- ✓ Health research investigator (Senior researcher)
- ✓ Other, please specify

5.1.2 Gender (Male, Female, Other)

5.1.3 Funding Record

You should also include your **5 most relevant funding** awards as Lead Applicant or co-applicant.

5.1.4 Mentor's Personal declaration

Briefly describe why you are well-suited to the role as mentor of the Lead Applicant. You should refer to expertise in

- ➢ Conducting research studies and applying research findings into and/or influencing policy and/or practice;
- ➢ Collaborating and Leadership;
- ➢ Capacity building, coaching and mentoring.

The word limit is **600 words**.

5.1.5 Research Outputs

Please reference up to 10 research outputs most relevant to this role as mentor (e.g. peer-reviewed articles, research data and datasets, research material, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence to health policy and practice, outreach and/or knowledge exchange activities, media coverage or other relevant activities). For non- peer-reviewed publications please add in the box below.

5.1.6 Total number of peer-review publications

Please provide the total number of publications which you have authored and/or co-authored and pubmed (or similar) link to your outputs page.

5.2 Collaborators

5.2.1 How many collaborators are you planning to engage in the fellowship's project?

The Lead Applicant can add up to 10 collaborators per application. Unlike the Mentor, 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 grants) relevant to this application where the collaborator has acted as Lead Applicant or Co-Applicant).

Relevant gatekeepers should be named as Collaborators within your application form if the success of a project is dependent on access to

- Healthy volunteers or patients
- Vulnerable population groups
- Data or databases
- Existing national or international study (e.g. an existing cohort or longitudinal study or a clinical trial)

5.2.2 Type of participant

Please describe yourself as:

- ✓ Health and social care professional with a joint or full academic appointment
- ✓ Health research investigator (Senior researcher)
- ✓ Stakeholder (charity, health organisation, patient group, policy maker, etc)
- ✓ Working in the private sector
- ✓ Other, please specify

5.2.3 Gender

Male, female or other

5.2.4 Collaborators' Role

Please detail the each collaborator's role during the fellowship and the percentage or proportion of a 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.

5.3. Collaborative and cross-disciplinary Approach

The application should have **inter-sectoral** and/or **cross-disciplinary**[14] 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**.

5.4 Mentorship arrangements

As Lead Applicant please describe why you have chosen the 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**

6. Research Project Description

The Project Description must include:

- 6.1 Research Question
- 6.2 Case for Research
- 6.3 Overall Aim
- 6.4 Objectives and Deliverables (plus Gantt or alternative)
- 6.5 Research Design and Methodological approach, including questions if applying for a feasibility study
- 6.6 Translational Pathway and Impact Statement
- 6.7 Dissemination and Knowledge Exchange Plan
- 6.8 Project Management
- 6.9 Public and Patient Involvement in the Research Project
- 6.10 Outline of FAIR Data Management
- 6.11 Gender Issues in the Research Project
- 6.12 Project description support file
- 6.13 References
- 6.14 Potential Risks, Ethical Concerns and Ethical Approval

[14] 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)**.**

6.15 Arrangements for Sample Collection for Biobanking (where appropriate)
6.16 Compliance with Data Protection Regulations (where appropriate)

6.1 Research Question

Clearly state the research question behind the proposed work. The word limit is **200 words**.

6.2 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 the problem to be addressed and the relevance to the policy and practice (locally, nationally or internationally); please reference any document/publications;
- ✓ Describe any systematic review or alternative evidence collected systematically supporting why this research project should be conducted now and include the knowledge gaps in the research area;
- ✓ 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.*

6.3 Overall Aim

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

6.4 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 the deliverables**.

You must upload a **Gantt chart** which lists the above objectives and deliverables against the estimated timelines for completion, together with any additional milestones/key dates (e.g. PhD submission).

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.

Are you applying for a feasibility study? Y/N

If you are applying to conduct a feasibility study you must address the section 5.6 and not 5.5

If you answer 'No' please address Q 6.5a and then move to Q6.6. Do not address questions in section 6.5.b (1 to 6)

6.5a 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.

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.
- The HRB-Trial Methodology Research Network (HRB-TMRN) mission is to strengthen the methodology and reporting of trials in health and social care on the island of Ireland so that they become more relevant, accessible and influential for patients and other service users, practitioners, policy makers and the public. We suggest that they be contacted at an early stage regarding methodology research relevant to trials **www.hrb-tmrn.ie** .
- 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 word limit is **4000 words**

If you answer 'Yes' to the feasibility study Q please address the questions 6.5b 1 to 6

6.5.b1 Research Design and Methodological Approach

Summarise the proposed research plan, providing descriptions of any individual work packages and describe how they integrate to form a coherent research project. 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 and the intervention, the methods of data collection, measures, instruments and techniques of analysis for quantitative and qualitative designs, outcomes measures, cost effectiveness and data analysis/management plans as appropriate.

Justify the **choice** of your planned intervention. Please consider following the TIDieR[15] checklist and guide for describing the intervention.

Describe and justify the **design** chosen, the methods you plan to use and the rationale of your choice. You are strongly advised to seek advice and input from an experienced research design and statistics expert at study design phase.

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

Please address the following and consider reviewing Appendix III:

- Please state explicitly the type of feasibility (see *Eldridge et al 2016*)
- What is the proposed study design (e.g. randomised or non-randomised, conventional parallel group RCT as opposed to cluster, factorial or stepped-wedge design etc.)?
- Describe the population to be studied
- What is the planned intervention?
- Have you fully described 'usual care' (if appropriate)?
- What are the proposed practical arrangements for allocating participants to study groups?

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

- What are the proposed methods for protecting against sources of bias?
- How variable is the intervention – between sites, over time etc.?
- Are there aspects of context and/or the environment which may impact on the evaluation being undertaken?
- What are the planned inclusion/exclusion criteria?
- Identify and explain how you address gender issues in your research. Define gender differences and inequalities, for instance with respect to accessibility or utilization of health care services.
- What is the proposed duration of intervention period?
- What is the proposed frequency and duration of follow up?
- Discuss the reliability and validity of all study instruments and scales
- What are the proposed primary and secondary outcome measures? For surrogate outcome measures, provide evidence of validity. State clinical relevance as well as relevance for the patient/target population.
- How will the outcome measures be measured at follow up?
- Are you planning to include health economics and quality of life measures? 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 and inclusion/exclusion criteria. In cases where one or both of these measures will not be addressed in this study, please explain why.
- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include for both control and intervention groups, a brief description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate
- What size of the difference is the trial powered to detect?
- What is the planned recruitment rate? How will the recruitment be organised? Over what time period will recruitment take place? What evidence is there that the planned recruitment rate is achievable?
- Are there likely to be any problems with compliance? On what evidence are the compliance figures based?
- What is the likely rate of loss to follow up? On what evidence is the loss to follow-up rate based?
- How many centres will be involved?
- Has acceptability testing been considered?
- What is the proposed type of analyses?
- What is the proposed frequency of analyses?
- Are there any planned subgroup analyses?

Notes:

- *The HRB encourages the development and application of agreed standardised sets of outcomes, known as 'core outcome sets', such as those reported by the COMET (Core Outcome Measures in Effectiveness Trials) Initiative.*
- *In cases where a member of the applicant team (including but not exclusively any industry partners) has previously been involved in the design and/or development of the product/service/application being*

evaluated (e.g. an App to deliver an education programme), the Lead Applicant must ensure that they clearly and explicitly explain any potential and/or perceived conflicts by addressing the following issues within the relevant sections of the application form:

- *Clarity on governance arrangements;*
- *Clarity on roles and responsibilities;*
- *Necessary assurances in relation to access to data, IP and publication of results/findings*
- *Any other important issue to be highlighted by the team*

- *You are advised to carefully address the potential benefits and difficulties presented by multi-site recruitment of patients or human subjects for the study in order to reach recruitment targets.*
- *Explain in detail how new techniques and/or or high-risk studies will be managed and suggest alternative approaches should these fail.*
- *Where new methods are being developed, arrangements for establishing validity and reliability should be described. Examples of non-standard questionnaires, tests, etc. should accompany the application or their content be clearly indicated.*
- *Useful links and resources are summarised in Appendix IV.*

6.5.b2 Studies within a Trial (SWATs)

Are you planning to include **Studies Within a Trial** (SWATs)? SWATs should address an independent methodology research question on the design, conduct, analysis, reporting or dissemination of trials for which there is current uncertainty. 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.

By way of examples, titles of published SWATs include:

- Site visits by the principal investigator to improve recruitment in a multicentre randomized trial.
- Timing and mode of delivery of a self-completion questionnaire.
- Gender of the person signing an invitation letter for a prospective study.
- Telephone screening versus face-to-face screening for the identification of participants in a multicentre trial.

The word limit is **500 words.**

6.5.b3 Internal Pilots

Are you planning to include an **Internal Pilot**? Internal pilots designed at the early stage of a definitive intervention trial can be included in the main study only where robust feasibility work has been completed. If yes, provide details of feasibility studies completed and results.

Internal pilot studies designate a portion of the main trial as a pilot phase. At the end of the internal pilot study, the investigators re-compute preselected parameters and recalculate required sample size. The study then proceeds with the modifications dictated by the internal pilot. Final analyses of the results incorporate all data, disregarding the fact that part of the data came from a pilot phase.

The word limit is **500 words.**

6.5.b4 Trial Management, Governance and Safety Monitoring

Arrangements for the management of the trials will vary according to the nature of the study proposed and should be proportionate to the complexity and associated risks. However, all should include an element of expert advice and monitoring that is **entirely independent** of the Lead Applicant, research team members and the institutions involved. Commonly, definitive trials are overseen by three committees: a Trial Management Group (TMG) a Trial Steering Committee (TSC) and an Independent Data Monitoring Committee (IDMC).

The role of these committees is to oversee the day to day management of the trial
Oversee the overall conduct and progress of the trial (including the safety data and the critical efficacy endpoints at intervals)

- Review relevant information from other sources
- Ensure adherence to protocol
- Consider interim analyses
- Advise whether to continue, modify or stop a trial and
- Provide the funding agency with information and advice.

A more detailed description of the roles of the three Committees can be found in Appendix V.

Applicants are asked to submit their proposed arrangements for overseeing the trial and suggested membership for each of the committee(s)

- Describe the role of each team member (e.g. sponsor, principal applicant, coordinator, trial statistician, research personnel, collaborators, CRFs) in the day to day management of this study, for all aspects of the study including recruitment, randomisation, management and retention of biological samples, delivery of intervention, follow-up, data entry, quality assurance, data management and analysis.
- Does the team involved in data management have adequate experience of data protection issues?
- Has adequate research design methodological expertise including statistical expertise been sought and incorporated within the team?
- It will be a condition of funding to register definitive interventions in an international register such as www.clinicaltrials.gov or www.isrctn.com/
- Describe the oversight, advisory or governance structures that will be established to oversee and monitor this trial; Trial Management Group (TMG) a Trial Steering Committee (TSC) and a Data Monitoring Committee (DMC)
- Provide terms of reference for these groups and proposed membership
- Outline the processes that will be put in place to ensure that the trial is well managed, commenting on project management, meeting schedules, financial management and monitoring etc.

The word limit is **2000 words.**

6.5.b5 Participants involved in the trial

In the following sections, please list (where already known) any members of your proposed management, governance and safety committees. A more detailed description of the roles of the three Committees can be found in Appendix V. This section is not compulsory as we understand some of the positions may not have been populated yet. The maximum number of members you can add to each of these sections is highlighted in bold at the end of each line.

- Trial Sponsor – list if there is any additional trial sponsor/funder for this study. **(5)**
- Trial Management Group – see Appendix V. **(10)**
- Trial Steering Committee – see Appendix V. **(5)**
- Independent Data Monitoring Committee – see Appendix V. **(10)**
- Trial Statistician – list the statistical expert(s) involved in any statistical analysis for the study. **(5)**
- Trial Supporting Facilities – list any infrastructures which may support the study. **(10)**
- Recruiting centres – list any sites that will be involved in recruitment of study participants. **(10)**
- Other participating groups/bodies – please list any additional affiliates of the study. **(10)**
- Review of trial protocol – Study protocols should be reviewed by an independent body to ensure an objective assessment/evaluation of the protocol prior to implementation. List the independent reviewer of the trial protocol. **(5)**

6.5.b6 Trial expertise in management, governance and safety committees

Does the research team include people with experience of successfully running large definitive trials?
Indicate trial expertise of all the above-mentioned participants by citing the 5 most relevant publications and/or specifying role in ongoing or previous trials(s). Ensure that the research team has the necessary expertise to carry out the study. The word limit is **500 words.**

6.6 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.
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 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.*

6.7 Dissemination and Knowledge Exchange Plan

Include a clear dissemination and knowledge exchange plan to indicate how the research outputs you anticipate producing during the life of the project will be disseminated and shared and, where possible, made openly accessible[16] [17] during and after your research, e.g. ***research articles***, ***research data***, ***dataset software code***,

[16] **http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/**
[17] **https://ec.europa.eu/research/openscience/index.cfm?pg=open-science-cloud**

algorithm, nanopublications[18]***, educational resources***, ***reports***, ***policy briefs and other relevant documents***. Who are the various audiences and communities internationally and nationally that need to be targeted if these results are to have any impact? What is your dissemination plan to address this? Describe academic publication plans and/or plans for technology transfer. 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. Describe how you will share and provide open access to any of the planned research outputs of the project, and their relative timelines.
Please reference if you are planning to use the HRB Open Research platform.
The word limit is **600 words**.

Note: The HRB is committed to facilitating and supporting open research practices (open access, open data and open source) as well as working towards the implementation of the recent EU recommendations on open research data[19]*.*

6.8 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**.

6.9 Public and Patient Involvement in the Research Project

PPI 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 carrying out the research.

Please 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 public involvement is likely to vary depending on the context of each study.
Provide information on the individuals/groups and the ways in which they will be involved. If you feel that this is not applicable to your application you must explain why. The word limit is **600 words**.

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

[18] A nanopublication is the smallest unit of publishable information: an assertion about anything that can be uniquely identified and attributed to its author **http://nanopub.org/wordpress/**
[19] **http://www.bluebridge-vres.eu/sites/default/files/HLEG%20EOSC%20first%20Report%20%28draft%29.pdf**

- 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 to increase participation in your research by making it more acceptable to potential participants

*Note: 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.*

6.10 Outline on FAIR Data Management

Good data stewardship is rapidly becoming an essential part of modern science and Data Management/Stewardship Plans (DMPs) are a key element of good research practice. At a national level Ireland is developing national principles and an approach for research data management, including the need for all funded research to consider a data stewardship/management plan (DMP). Also HRB will shortly announce an open publishing platform, HRB Open Research, that will support researchers to work in a more open manner, and also include the need for supporting data alongside publication.

Please address the following questions regarding the management of the research data during your programme. Please consider the FAIR Guiding Principles for scientific data management and stewardship: Findability, Accessibility, Interoperability, and Reusability[20,21]. The word limit is **600 words.**

- The handling of research data during and after the end of the project;
- What data will be collected, processed and/or generated?
- Which methodology and standards will be applied?
- Whether data will be shared/made open access? If data cannot be made available, please explain why (e.g. safeguarding commercial interests, personal information, safety or security of the data);
- How data will be curated and preserved (including after the end of the project)?

***Note:** You are not currently required to develop or submit a full DMP as part of this application although we strongly encourage successful applicants to do so as a key element of good research practice. Where it is envisaged that a Data Management Plan (DMP) will be created after please indicate this here, and include the timing and delivery of the DMP and any planned revisions within the project deliverables.*

***Note:** If you are unfamiliar with the FAIR Guiding Principles or Data Management, please liaise with local supports available (e.g. library, research office, IT) within your institution for guidance. Any resources and costs associated with research data should be planned and costed accordingly in the budget.*

[20] **https://www.force11.org/group/fairgroup/fairprinciples**

[21] 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) **http://www.nature.com/articles/sdata201618**

Links to useful resources are summarised in Appendix II.

6.11 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.*

6.12 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[22]:

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

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

6.13 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.**

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

6.14 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 (including work involving animals) 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.**

6.15 Arrangements for Sample Collection for Biobanking

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

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, and describing data protection measures where appropriate. Please reference relevant guidelines/standards you will use. Where material will be obtained or stored for a *future research purpose*, or where you will use material *previously obtained* for another purpose, please refer to the latest Recommendation of the Council of Europe[23]. Some useful links are in Appendix III. The word limit is **400 words.**

6.16 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.**

7. Research & Professional Development Plan

7.1 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 in working in the proposed research area as well as taking an active role 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 to discuss the proposed training plan with the mentor.

The word limit is **600 words.**

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

7.2 Research and Professional 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

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

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.*

***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.*

7.3 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 apply now, as requests for travel-related costs to gain research experience abroad during the course of the fellowship will not be considered. You may apply for up to six months abroad and a maximum of €6,500.

Within the overall plan, agreed with your sponsors, mentor and employer, 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 HRB recognises the difficulties associated with longer trips abroad while maintaining a clinical post. Shorter visits and trips will be considered where appropriate and justified.

Note:

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

- *You **must** upload a signed Letter of Support on headed notepaper as evidence of the Sponsors willingness to allow you to gain experience in their Department/Institution.* ***If this letter is not uploaded at the time of submission, the travel grant component will not be considered as part of your application.*** *Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system. Please label this upload clearly e.g. "Travel Grant Sponsor - Prof P Smith".*

8. Institutional and Infrastructural Support

8.1 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.**

8.2 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.

9. 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.***

Funds will be provided for the following:

1. **Personnel costs**	Must be listed for each salaried personnel under each of the following subheadin (a-e):
a) Salary	Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with host institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scale for academic researchers **http://www.iua.ie/research-innovation/researcher-salary-scales.** Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure. Please state the pay scale used and the level and point on the scale. The maximum scale is the **Level 2 Point 10 for the ARPP-A and Level 3 Point 4 for the ARPP-P**. Applicants can allow for annual salary scale point increases. **Note:** The HRB does not provide funding for the salary or benefits of academic staff within research institutions who are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators.
b) Employer's PRSI	Employer's PRSI contribution is calculated at 10.75% of gross salary.
c) Employer Pension Contribution	Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution. If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
2. **Running Costs**	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, 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, biobanking, Clinical Research Facility support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form' upload. 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 etc. should be charged to running costs. Costs related to research data management for the duration of the project should be charged to running costs. The following costs are ineligible and will not be funded: training courses/workshops for funded research personnel, inflationary increases, cost of electronic journals. Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs. **The maximum amount requested is €30,000** over the lifetime of the fellowship **with additional €10,000** when properly justified.
3. Equipment	Funding for small items of equipment can be included in this section. Stand-alone computers will not be funded. All costs must be inclusive of VAT, where applicable. **The maximum amount requested is €2,000** over the lifetime of the fellowship
4.Training costs	Linked to 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 **The maximum amount requested is €3,000** over the lifetime of the fellowship
5. Dissemination Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[24]. **The maximum amount requested is €3,000** over the lifetime of the fellowship.
6.Travel Grant/Research Experience Abroad	You may request a contribution of **up to €6,500** over the lifetime of the fellowship 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.

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

7. Overhead Contribution	In accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for **laboratory or clinically-based research** and 25% of Total Direct Modified Costs if **desk-based research.** The following items are included in the overhead contribution: recruitment costs, bench fees, office space, software, contribution to gases, bacteriological media preparation fees, waste fees, bioinformatics access.

10. Approvals

10.1 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.

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

10.2 Clinical Trial Approval, if applicable

Clinical Trial Approval from the Health Products Regulatory Authority is required for trials involving medicinal products. Necessary authorisations for trials involving medical devices differ depending on the device. Applicants are responsible for ensuring that all necessary approvals are in place prior to the start of the research.

10.3 Sponsorship for Clinical Trial Applications, if applicable

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HRB cannot take on the role of sponsor. Plans for appropriate sponsorship arrangements must be included in the application i.e. Letters of Support must be provided from sponsors or potential sponsors.

***Note:** If any of the following documents, ethical approval and/or clinical trial approval and/or hospital approval, have already been secured for this grant you will be requested to upload a copy of the relevant approval letter later in this application.*

***Note:** Applicants should allow sufficient time to obtain ethical and/or competent authority 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*

11. Other Funding Sources

11.1 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.**

11.2 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.**

12. Submission of Applications

The deadline for submission of complete applications is 15 March 2018 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 assess the 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

USE OF ANIMALS IN RESEARCH

Experimental Design Assistant (EDA) (online tool for design of animal experiments)
https://www.nc3rs.org.uk/experimental-design-assistant-eda

ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines
https://www.nc3rs.org.uk/arrive-guidelines

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

Digital Curation Centre: How to develop a data management and sharing plan and examples DMPs
http://www.dcc.ac.uk/resources/data-management-plans/guidance-examples

UK Concordat on Open Research Data (July 2016)
http://www.rcuk.ac.uk/documents/documents/concordatopenresearchdata-pdf/

Guidelines on FAIR data management plans in Horizon 2020
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

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

FAIR at the Dutch centre for Life sciences
http://www.dtls.nl/fair-data/fair-data/

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

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