Comhairle na nDochtúirí Leighis
Medical Council

HRB Health Research Board

THE PATRICK QUINN AWARDS for PARKINSON'S RESEARCH

PQA FUNDING SCHEME 2019

Guidance Notes

Key Dates & Times

PQA Call Open	**10 December 2018**
PQA Application Closing date	**21 February 2019 at 13:00**

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Guidance Notes

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1. Introduction

The HRB is the lead agency in Ireland supporting research linked to health and social care. During the period of the *HRB Strategy 2016-2020: Research. Evidence. Action.* the HRB has committed to strengthen and develop partnerships within academia, practice and policy spheres to accelerate the translation of research into real benefits for people and play a key role in health system innovation, transformation and economic development. The HRB now wishes to run a call for research proposals on behalf of and in partnership with the Medical Council supported by a bequest from the late Mr. Patrick Quinn to the Medical Council who wished for a sum of his estate to be invested into research on Parkinson's Disease.

The Medical Council is the regulatory body for doctors. It has a statutory role in protecting the public by promoting the highest professional standards amongst doctors practising in the Republic of Ireland. The Medical Council maintains the Register of Medical Practitioners - the Register of all doctors who are legally permitted to carry out medical work in Ireland. The Council also sets the standards for medical education and training in Ireland. It oversees lifelong and learning and skills development throughout doctors' professional careers through its professional competence requirements. It is charged with promoting good medical practice.

Given the HRB mission of improving people's health, and to enhance healthcare delivery, and the experience and expertise of the HRB in peer-reviewing and managing research, the HRB will manage the application and peer-review process, as well as the awards, on behalf of the Medical Council. In addition to the bequest from the late Mr Quinn, HRB will provide co-funding for the projects funded.

Parkinson's Disease (PD) is the second most common neurodegenerative disease, after Alzheimer's. Incidence increases rapidly over the age of 60[1]. Studies of incidence and prevalence data vary across countries[2], and it is acknowledged that there has been no significant epidemiological studies in Ireland of Parkinson's Disease[3]. Globally numbers living with a diagnosis of PD are expected to increase significantly over the coming decade[4],[5] with contributions including an ageing population, increases in life expectancy and potentially environmental factors playing a part.

[1] https://www.parkinsons.org.uk/sites/default/files/201801/Prevalence%20%20Incidence%20Report%20Latest_Public_2.pdf

[2] Von Campenhausen S. et al. Prevalence and incidence of Parkinson's disease in Europe. *Eur Neuropsychopharmacol.* 2005; 15: 473-490

[3] https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/neurology-model-of-care.pdf

[4] Dorsey E. R. et al. Projected number of people with Parkinson disease in the most populous nations, 2005 through 2030. *Neurology* 2007; 68 (5)

People with Parkison's can typically experience both motor and non-motor symptoms[6], which can change as the disease progresses, and depending on medication taken. Some motor problems experienced are tremors, slow movement, shuffling walk, and freezing of movement. There are also many non-motor symptoms which can range from sleep disturbances, changes in mood, constipation, changes in personality and impulsive behaviours. People diagnosed with Parkinson's will typically need a range of medical and other interdisciplinary care support including physiotherapy, occupational therapy, speech and language therapy, nutritionists, and specialist nursing care. Many people in Ireland access care through community-based or patient associations. Self and family management strategies for PD is also important for those living with Parkinson's to promote independence and quality of life. Management has to be tailored depending on people's age, particular symptoms and preferences.

The Patrick Quinn Awards for Parkinson's Research scheme aims to fund teams to conduct excellent research which will have direct relevance in the short-term for people with Parkinson's, their families or carers, or the health care professionals and other organisations who are involved in delivering health and social care for this patient population.

The focus of research should be to improve health outcomes, as well as to deliver benefits and improvements to the lives of people with Parkinson's, their families and carers in Ireland. This could focus on symptom improvement, improving quality of life, and research on access to health and social care within the Irish system. In line with identified gaps in knowledge raised by the Parkinson's Association, research relating to the epidemiology of Parkinson's disease in Ireland is also invited.

Towards this end, the Patrick Quinn Awards for Parkinson's Research will support **a number of national projects over a 1-2 year period**.

Applications can come from any HRB-recognised Host Institution in the Republic of Ireland, with research to be conducted in Ireland; however proposed research must be able to demonstrate high *relevance* in the short-term for people affected by Parkinson's, or those who deliver their healthcare. Lead Applicant: Researchers do not need to have a track record in Parkinson's research, but may transfer expertise gained in other areas into this disease area.

The HRB and Medical Council are keen to encourage a strong sense of collaboration with an emphasis on a "partnership" approach, and will support research projects which involve people with Parkinson's, families and carers working together with researchers, patient organisations, and healthcare/community organisations as appropriate.

The level of Public and Patient Involvement in the projects is expected to be significant, **in particular it is expected that people with Parkinson's, their families or carers will have had a role in identifying the need for the proposed research.** Furthermore it is expected that **the applicant team will have representation from people with Parkinson's, family members or carers or a patient**

[5] Dorsey E. R. et al. Global, regional, and national burden of Parkinson's disease, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet Neurol* 2018; 17: 939–53 **DOI:** https://doi.org/10.1016/S1474-4422(18)30295-3

[6] https://www.parkinsons.ie/aboutparkinsons

representative organisation – to ensure appropriate representation of those affected by Parkinson's throughout the project. The Panel making a funding recommendation to the HRB Board will represent not only scientific members but also Panel members with a particular focus on Public and Patient Involvement (PPI) in research. A separate scoring criterion will be used for Relevance including PPI, equally weighted with Scientific Merit and Knowledge Translation.

The format used for this scheme will be based on the HRB Applied Partnership Awards, with applications invited from a Lead Researcher and Lead Knowledge User. This is to ensure that proposed research will directly address health and social care needs in relation to Parkinson's and that research findings are applied in as short a time as possible.

Engaging 'knowledge users' in the research process from idea formulation through to dissemination and implementation has been proposed as the funding model most likely to ensure that research findings are relevant and responsive and can influence decision making in the health and social care system[7],[8]. A **knowledge user** is defined as one in a position of authority to influence and/or make decisions about health policy or the delivery of services and can act to ensure that the findings of the research will be translated to influence decision making and change within their (or other) organisations.

Knowledge user organisations are typically Government departments, agencies, hospitals, local government, voluntary organisations, research charities, patient/consumer groups or other organisations involved in making decisions regarding the management, structuring and/or delivery of practice or policy in the Irish health and social care system.

In the context of this scheme which is focused on Parkinson's Research, the Knowledge User could be based within a relevant patient group, a voluntary organisation, a health-system manager, a relevant policy-maker, or could be a health professional or clinician who is in a position to make significant changes to policy or practice relevant for people with PD.

To describe academic/knowledge user partnership funding models the Canadian Institutes of Health Research (CIHR) coined the term 'integrated knowledge translation' (iKT)[9] and differentiated this from end-of-grant knowledge translation (KT). Based on what is known about the most effective iKT approaches[10] this scheme requires that knowledge users are involved as active partners throughout the research process and that the knowledge users are willing to invest time and resources to the successful completion of the research.

[7] Sibbald S.L. et al. Research funder required research partnerships: a qualitative inquiry. *Implementation Science* 2014. 9:176.
[8] Rycroft-Malone J. et al. Collective action for knowledge mobilisation: a realistic evaluation of the Collaborations for Leadership in Applied Health Research and Care (CLAHRC), Health Services and Delivery Research, 2015 Vol 3; No 44. http://www.journalslibrary.nihr.ac.uk/hsdr/volume-3/issue-44
[9] Guide to knowledge translation planning at CIHR: integrated and end of grant approaches [http://www.cihr-irsc.gc.ca/e/45321.html]
[10] Best A., Holmes B. J. Systems thinking, knowledge and action: towards better models and methods. *Evidence and Policy* 2010 Vol 6, No 2, 145-149.

The Patrick Quinn Awards for Parkinson's Research scheme is based on the premise of iKT, partnership and co-production. This scheme provides support for research projects that are clearly focused on the needs of people in Ireland with Parkinson's, their families and carers, including health services research that addresses their needs.

On behalf of HRB and the Medical Council, using the generous gift from the late Mr Patrick Quinn, the HRB are now inviting applications for the PQA Funding Scheme 2019.

1.1 Aims and Objectives

The overarching **aim** of the Patrick Quinn Awards for Parkinson's Research scheme is to support high quality applied research projects where academic researchers and knowledge users come together in a collaboration to focus on themes/questions which have been developed in consultation with people affected by Parkinson's. The focus of the health research projects should be to improve health outcomes, as well as to deliver benefits and improvements to the lives of people with Parkinson's, their families and carers in Ireland.

Research should have direct relevance in the short-term (within 2 years after the end of the award) for people with Parkinson's, their families or carers, or the health care professionals or other organisations who are involved in delivering health and social care.

The **objectives** of the Patrick Quinn Awards for Parkinson's Research are to:

- support high quality research that is priority-driven and nationally relevant
- support applied projects, i.e., that have the potential for application/impact on people's health care, policy and practice decision-making within a relatively short timeframe (within 2 years after the end of the award)
- actively engage people with Parkinson's, their families or carers in identifying research priorities and throughout the research process to ensure issues addressed are relevant, timely and responsive to their needs
- engage knowledge users in the research process from question selection through to conduct, dissemination and action to ensure that the issues addressed are relevant, timely and responsive for the Irish healthcare system
- encourage a partnership-based model to optimize the likelihood of the research evidence being applied.

1.2 Scope

This scheme provides funding for clearly defined research projects in clinical and/or population health and/or health services that are relevant to people with PD in Ireland.

Awards will be made at a level of **between €100,000 and €250,000** (inclusive of overheads) for projects from 12 up to 24 months duration. Applicants are advised to closely match duration and requested budget to the scope of the research.

The research question is expected to have been influenced by and informed by people with Parkinson's Disease, and the question/s must be able to be answered by the research partnership. This may also be informed by resources such as the James Lind Alliance Priority Setting Partnership[11] Findings from the research are expected to have a direct impact on the decision-making of the knowledge user's organisation/s, and it should be clear from the application how the knowledge user/s is integrated throughout the research process. Each application should include a clear and concise knowledge translation plan that will highlight how the research findings will be applied by the knowledge user organisation/s.

Proposals addressing the following are particularly welcome:

- Improving activities of daily living for people with Parkinson's
- Self and family management tools and approaches for PD
- People with Parkinson's, families' and carers' experience of healthcare provision/access, as well as means to improve their experience
- Epidemiology of PD in Ireland
- Delivery and organisation of care at community, primary care or hospital level
- Integrated care, with doctors, nurses, health & social care professions, patients, families and patient organisations working together in a collaborative way to improve the patient journey
- Models of care involving multiple sites
- Health service developments/reconfiguration

This PQA call will **not support**:

- Application in any disease area other than Parkinson's
- Applications involving basic biomedical research
- Pre-clinical research
- Researcher-led research projects that seek to address a major health challenge and which are primarily aimed at adding to the international scientific knowledge base. While the research proposed in these awards may add to the scientific knowledge base this is not a requirement and should not be the primary aim. Investigator-led research addressing major health challenges that are aimed at adding to the scientific knowledge base are funded through other HRB schemes such as the Investigator-Led Projects.
- Trials or interventions. Definitive Intervention or feasibility studies as are out of scope as these are supported by the HRB Definitive Intervention and Feasibility (DIFA) studies awards[12]
- Technology development, although technology usability/re-purposing, and uptake can be considered
- Applications which are solely literature reviews, audits, surveys, needs assessments (although these elements may be part of an integrated research study)

[11] http://www.jla.nihr.ac.uk/priority-setting-partnerships/parkinsons/top-10-priorities/

[12] Eldridge S. M. et al. Defining Feasibility and Pilot studies in preparation for Randomised Controlled Trials: Development of a conceptual Framework. *PLoS ONE* 2016 11(3): e0150205

- Applications which are solely **or** predominately developing the infrastructure for biobanking, databases or patient registers without a predominant research element
- Applications which are solely **or** predominately health service developments without a predominant research element. The scheme will not fund the cost of providing the service 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

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

Guidance notes on the application form are available in Appendix I.

2. Eligibility Criteria of Lead Applicants, Co-Applicants and Collaborators

Applications should be made on behalf of a team which is made up of researchers, knowledge users and people with Parkinson's, family members or carers or a relevant patient representative organisation/charity (PPI contributors). The applicant team should designate a Lead Applicant from the research team, a Lead Applicant from the Knowledge User team, and a Lead PPI Contributor. While we acknowledge that there are many individuals in Knowledge User organisations that are also experienced researchers, it is important in this scheme that there are distinct Lead Applicants. Where the knowledge user represents a voluntary group or patient organisation it is expected that service users, family members or carers are represented separately.

The applicant team must demonstrate clearly that the appropriate and relevant partners are involved in order to achieve the objectives set out in the research proposal and in a manner that aligns well with the sections included in the application on relevance, knowledge translation plan and impact.

The HRB expects that applicants will collaborate, where appropriate, with partner organisations, such as universities, hospitals, health agencies, local government and or voluntary organisations.

2.1 Lead Applicant: Researcher

The Lead Applicant (LA) will serve as the primary point of contact during the review process and during the award. The LA will be responsible for the scientific and technical direction of the research programme and 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 contract governing the award.

The Lead Applicant must

- Hold a post that covers the duration of the award in a recognised Research Institution as an independent investigator, **or**
- be a contract researcher recognised by the Research Institution as an independent investigator who will have a dedicated office and research space for the duration of award, for which he/she will be fully responsible, **or**
- be an individual who will be recognised by the Research Institution upon receipt of the PQA award as a contract researcher as defined above. The Lead Applicant does not necessarily need to be employed by the Research Institution at the time of the application submission

The Lead Applicant must demonstrate that they have the skills, knowledge and supports necessary to direct the proposed research and to be actively engaged in carrying the research through to completion. The LA must:

i. Show appropriate evidence of expertise matched to the nature and context of the project;
ii. Show evidence of achievement as an independent researcher in their chosen research field by:
    a) Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs such as published book chapters, reports to government and/or any other relevant outputs that have resulted in a significant impact in their field.
    b) Demonstrating record of independence by showing that they have secured at least one peer-reviewed research grant for a research project/s, as either the lead applicant or a co-applicant. Funding received for travel to seminars/conferences and/or small personal bursaries will not be considered in this regard.
iii. Show evidence that they possess the capability and authority to mentor, manage and supervise less experienced researchers and to manage relationships with co-applicants, collaborators and the host institution.

2.2 Lead Applicant: Knowledge User

While there may be one or more knowledge user organisations involved, the **Lead Applicant-Knowledge User** should coordinate the application process and provide details on the strategic relevance of the project in the context of Parkinson's Disease in Ireland. They should describe how the question was formulated, refined and agreed. They should describe how their roles and position will enable them to influence change and action the outputs of the research project. The Lead Knowledge User should summarise what prior experience (if any) they have of working with researchers, their plans for collaboration throughout the research process and the time and resources they are committing to the project.

2.3 Lead Applicant: PPI contributor

The Lead PPI contributor should be a person directly affected by Parkinson's as a person with Parkinson's, a family member, carer, or represent an organisation representing Parkinson's patients. The Lead PPI contributor will be asked to set out the PPI contribution to developing the research question, and the PPI plans for the project. The Lead PPI contributor should summarise what prior

experience (if any) they have of working with researchers, their plans for collaboration throughout the research process and the time they are committing to the project.

For the purposes of contracting, payment and management of the award, and because HRB funds can only be awarded to a HRB approved Host Institution in the Republic of Ireland, the award will typically be managed by the Host Institution of the Lead Applicant-Researcher.

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

Only one application per Lead Applicant Researcher to this scheme will be considered. However, Lead Knowledge Users and Lead PPI contributors may participate in more than one application.

2.4 Co-Applicant

Co-Applicants will be asked to select whether they are a **Researcher co-applicant or a Knowledge User co-applicant** for the purpose of the proposed research. Up to a maximum of 10 **Co-applicants** can be included. It will be up to the Lead Applicants to decide on the balance of researchers and knowledge users that will make up the research team.

A Co-Applicant has a well-defined, critical and substantial role in the conduct and steering of the proposed research. Co-Applicants from outside of the Republic of Ireland are welcome where the nature of the research renders this necessary and is appropriately justified. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards his/her own salary if they are in salaried positions. However, **Researcher Co-Applicants** can request their own salary, depending on their role and percentage of time dedicated to the research project, for the duration of the award if they are contract independent investigators. PPI participants in the project should be named as Co-applicants.

Note: It is not mandatory to have 10 Co-Applicants but this is to allow for flexibility should this seem appropriate.

The terms of any co-application should be determined early and relevant agreements should be in place by the onset of the project. The PQA advise that consideration should be given to issues such as governance arrangements, intellectual property rights, reporting and access to data and samples when working up co-application agreements.

2.5 Official Collaborator

An official Collaborator is an individual or an organisation who provides an integral and discrete contribution (direct or indirect) to the proposed research. A collaborator may supply material, may provide training, access to specific equipment, specialist staff time, 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. Collaborators may be based outside the Republic of Ireland where appropriate and justified. Collaborators are eligible to receive funding from the award when properly detailed and justified **(up to a maximum of 10 Collaborators can be listed)**.

If access to vulnerable population groups, healthy volunteers or patients, data, databases or a link to an existing national or international study (e.g. an existing cohort or longitudinal study) are an integral part of the proposed project, evidence of commitment and access must be demonstrated by having the key Gatekeeper of this data or study included as a Collaborator. This will greatly assist the reviewers and panel members in reviewing aspects of commitment, access and overall project feasibility.

In addition, each official collaborator must complete a **Collaboration Agreement Form.**

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.

3. Funding

PQA awards are expected to be between €100,000 and €250,000 inclusive of research overheads. **The maximum budget is €250,000** for projects from 12 months up to 24 months in duration.

Eligible costs include personnel costs, direct running costs, FAIR data management costs, dissemination costs and overhead contribution.

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

Members of the public/patients must be compensated for their time and contributions.

3.1 Release-Time for Knowledge Users

Salary-related funding may be requested from the HRB to enable the release time for knowledge users up to the value of €20,000 per year**.** The €20,000 per year release time funding can be used in full (if required) to fund the participation of one knowledge user applicant/co-applicant or it can be allocated between the knowledge user applicant and a number of knowledge user co-applicants if required. The individual/s for who the release time allowance is requested must meet all the following criteria:

- Be a knowledge user applicant/co-applicant on the award whose primary responsibilities/role specification do not include an expectation to engage in research (i.e. as part of their regular employment);

- Have a clear plan setting out the tasks and activities they will be involved in and how this will add value to the overall aims of the project and its application;
- Have secured their organisations approval for the release time on the project that would justify the allowance and have their organisations certify in a **Letter of Release-time approval** that they are/will be engaged in the activities for which the funds have been requested;
- Will be replaced for the period of time spent on the project by another person, i.e. the award will cover the cost of back-fill for that person.

Note: The scheme does not fund the salary and related costs of tenured academic staff within research institutions (including buy out from teaching time etc.). It is expected that PPI contributors will be recompensed for their time.

Note: As the primary aim of this scheme is to fund high quality, innovative research projects of international standing, applicants must demonstrate clearly that the level, expertise and experience of proposed research personnel matches the ambition and scale of the project, and that they possess the necessary breadth and skills in all methodological areas required to deliver the proposed programme of work.

4. Public and Patient Involvement in Research (PPI)

The HRB *Strategy 2016 – 2020: Research. Evidence. Action.* includes a commitment to develop and promote public and patient involvement (PPI) within the HRB and in HRB-supported projects and programmes. We use the definition of PPI proposed by INVOLVE UK (www.invo.org.uk)**: *Research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them.*** We also use the INVOLVE definition of the term 'public' which includes patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services.

'Public and patient involvement' represents an active partnership between members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research. The HRB encourages a comprehensive approach to PPI. Those for whom benefit is intended should be at the heart of decision-making within the project.

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 a service or living with a health condition
- make the language and content of information such as questionnaires and information leaflets clear and accessible
- help to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants
- help to ensure that the research uses outcomes that are important to the public

- identify a wider set of research topics than if health or social care professionals had worked alone
- help you increase participation in your research by making it more acceptable to potential participants.

In addition to improving relevance and quality of research, it ensures that research is influenced by broader principles of citizenship, accountability and transparency.

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.

In the application, you are asked to describe public or patient involvement in your research throughout the various stages of research design and planning, conduct, analysis and dissemination. We recognise that the nature and extent of active public involvement is likely to vary depending on the context of each study or award. In this application, you **must describe** (i) public involvement to date, (ii) how that has influenced/changed what work has been planned, and (iii) public involvement planned for the duration of the award.

There will be PPI Panel members assessing applications in this scheme and a separate scoring criterion will be used for Relevance including PPI, equally weighted with Scientific Merit and Knowledge Translation.

A number of useful resources for guiding researchers on public involvement in research are provided in Appendix II including the Public Involvement Impact Assessment Framework (PiiAF), through which researchers can explore approaches to PPI and assess the impacts of involving members of the public in their research, and a Handbook developed by the European Patient Forum with practical examples for Lead Applicants of ways in which patients can be involved at different stages of a research project. **Where members of the public/patients are involved, they must be compensated for their time and contributions.** Patients/public must be part of the lead applicant team and can be included as co-applicants as appropriate to the project.

5. Host Institution

HRB will issue the contracts for successful awards. A *HRB Host Institution*[7] 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. In order to be eligible to apply for funding, an Institution must be an approved HRB Host Institution no later than two calendar months before the closing date of a call. Information is available on the HRB

website on the application process for research performing organisations to be approved as HRB Host Institutions[13].

Host Institution Letters of Support must be provided for **(1) all Lead Applicants in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary.** The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*Host Institution – insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB PQA award as a contract researcher; (ii) has an independent office and research space/facilities for which he/she is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise post-graduate students and post-doctorate researchers. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

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

6. FAIR data management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support open research[14] and open publishing directly through the HRB open research platform[15]. The HRB is now driving the making of research data **FAIR** (**F**indable, **A**ccessible, **I**nteroperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability. The FAIR data principles[16] provide a guideline for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals.

For researchers, the move to FAIR and open data means researchers should consider data management issues and and find suitable data repositories at the research planning stage. Applicants will have to provide information about their plans for data management and data sharing at application stage.

7. General Data Protection Regulation

The **General Data Protection Regulation** (GDPR) came into force on 25 May 2018. As a result the applicant team will be asked through GEMS to **confirm you understand** that personal data provided as part of this application, including but not limited to CV information, may be shared with person(s) based outside of the European Economic Area (EEA) for the specific purpose of obtaining peer

[13] http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/
[14] http://www.hrb.ie/funding/policies-and-principles/open-research/
[15] https://hrbopenresearch.org/
[16] https://www.force11.org/group/fairgroup/fairprinciples

reviews of this application. International reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Individual peer reviewers are selected for their specific expertise in relation to submitted applications, and can be based anywhere in the world.

Furthermore, by confirming participation, you will be asked to **confirm you understand** that the HRB uses the information you provide (regarding all applicant team members) to consider your application, contact you about your application, and if you are successful, to manage your grant throughout its lifetime in accordance with HRB general Terms and Conditions for research awards. This will include contacting you with regard to monitoring of progress through written reporting and other means e.g. interim review. We will publish some basic information on successful awards including PI, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended we will continue to keep your information on file (in accordance with HRB policies) to allow us to evaluate the outcomes, outputs and impacts of HRB investment in your research.

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

8. Application and Review Procedure

8.1 Application Procedure

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

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

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

8.2 HRB Gender Policy

The **HRB Gender Policy** came into effect on 1 June 2016[17]. To ensure fairness and equality to all applicants, each funding application received will be assessed as outlined in the call guidance documentation for that particular funding round. To ensure gender balance in decision-making, the HRB aims to reach the international best practice target of 40% of the under-represented gender in all HRB panels where possible. Gender will also be considered when appointing the position of Panel Chair.

Peer Reviewers may be selected with expertise of sex/gender issues for the topic of your proposal. Gender balance of the Lead Applicant of the research team will be among the ranking factors to prioritise proposals with the same scores in the Panel ranking list.

8.3 Peer review

Following an initial eligibility check, the proposals submitted to this scheme will undergo a two phase review process. The first phase will include an online international peer review approach assesses the strengths and weaknesses of the application relating to the Scientific Merit criterion only, as detailed in Section 8.5. As well as providing a score for Scientific Merit, peer-reviewers will be able to comment on knowledge translation and relevance if they wish. Applicants will be expected to score highly on Scientific Merit in order to move forward to the next review phase. Depending on the number of applications received, the PQA may short list applications based on the scores received from the international reviewers.

8.4 Response to reviewers

Short listed Lead Applicants with the support of his/her team will be provided with a time-limited opportunity to respond to peer-reviewers comments. The peer-reviewers comments will be made available to PIs by email. Each applicant team will have **10 working days only** to submit their response through GEMS, and the response has a maximum word count of **2000 words**. The response will be provided to members of the Panel in advance of their face-to-face meeting alongside the application and the peer-reviewers' comments.

There is no obligation to submit a response but this phase of the assessment process is extremely important and the response may play a critical role in whether a proposal eventually gets recommended for funding or not. It provides an opportunity to address any factual errors, conceptual misunderstandings or differences of opinion that can be perceived as weakness or concerns. It also provides the applicant team with an opportunity to take on board any constructive feedback that may help to improve the application, if funded, or future grant applications.

The response should be succinct yet clear and comprehensive. It should acknowledge and/or address all of the significant concerns and/or weaknesses described in the reviewer's feedback. If the applicant team disagrees with a reviewer's statement they should explain why and provide additional information. If the applicant team cannot address an issue, they should at least

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

acknowledge it. Responses that could be seen as argumentative should be avoided. Remember that peer reviewers and panel members volunteer their own time in reviewing grant applications.

Lead Applicants should ask a colleague to read the reviewers' critiques and the responses prior to resubmission, to confirm that they have addressed the critique in a way that is informative and constructive.

Following feedback and commentary from online reviewers, an international grant selection Panel will be convened to discuss applications.

8.5 Panel meeting

A Panel will be convened consisting of international researchers, knowledge users and patient representatives. Each application will be assigned to a scientific panel member to review the Scientific Merit, a knowledge user panel member to review Knowledge Translation, and a patient representative panel member, to review Relevance, according to the assessment criteria for the scheme. Following a Panel discussion the final scores for each criterion will be combined to produce an overall consensus score. Successful applications will be expected to be score highly on each assessment criterion before being recommended for funding. Applications recommended for funding are submitted to the Board of the HRB for approval. It is expected to fund between five and seven projects, depending on quality and requested budget.

The reviewers will evaluate all applications based on the following *assessment criteria,* as approved by the HRB Board.

Scientific merit

- *Clear research question*
- *Strong need for proposed project supported by evidence*
- *Design and methodology appropriate*
- *Research team expertise and experience relevant for project*
- *Project plan and risk mitigation for project delivery*

Knowledge translation

- *Likely translation of findings beyond research setting*
- *Knowledge user expertise and experience relevant for project*
- *Planned knowledge dissemination and translation*

Relevance

- *Relevance for people with PD/their families/carers, or relevant health services*
- *Appropriate public and patient involvement in research*

The Panel reserves the right to support a balanced portfolio of projects, e.g. research addressing different types of research (across Clinical/Population health and Health Services Research).

The identity of the experts who participate in the peer review process shall remain confidential and shall not be disclosed to the Lead Applicants. A summary of Panel member's comments and the panel discussion comments will be issued to the Lead Applicant following the conclusion of the review process.

9. Timeframe

10 December 2018	Call Opens
21 February 2019	Call Closes
May 2019	Panel Meeting will take place in June 2019 with a view to making final recommendations to the Board of the HRB in June/July 2019
July 2019	Following approval of the recommendation by HRB Board, successful applicants will be notified of their success from July 2019
August 2019	Contracts will be issued from August 2019 with a view to beginning the research projects from Sep/Oct 2019
Sep/Oct 2019	Earliest Research Project Start Date

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 Applicants to provide all supporting documentation within the submission. If the documentation is not received by the HRB on time, in the correct format or is not properly signed or submitted, the application will be deemed ineligible without further review.

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's procedure for appealing funding decisions is available at http://www.hrb.ie/funding/funding-schemes/before-you-apply/relevant-policies/

10. Contact

Dr Kit Chan
Project Officer
Health Research Board
e kchan@hrb.ie
t +353 1 2345 181

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

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 Notes for further information.

The **Lead Applicant-Researcher** must create the application but it can then be jointly completed with the **Lead Applicant-Knowledge User, the Lead Applicant PPI Contributor,** and 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 Applicants 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-Researcher selects the PQA scheme 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-Researcher must satisfy the conditions of this check list.

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

Lead Applicant Declaration

Agreement to share personal data in application

I consent that personal data provided as part of this application, including but not limited to CV information, may be (a) shared outside of the European Economic Area (EEA) for the purpose of international peer review, and (b) the use of my data for assessment of my application; monitoring of successful awards; and evaluation of HRB's approach to funding and investment in research, in line with HRB policies and as detailed in the PQA Call Guidance Notes. Y/N

1. Host Institution and Signatory Notification

1.1 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 Researcher** but it may be another organisation/institution designated by the research team, where it is clearly justified. In order to be eligible to apply for funding, an Institution must be an approved HRB Host Institution no later than two calendar months

before the closing date of a call. Approved HRB Host Institutions are listed on our website[18]. Information is available on the same webpage on the application process for research performing organisations to be approved as HRB Host Institutions.

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 HI, you will be assisted with auto-select options. It is important that the HI name is entered accurately and in full as an incorrect entry may result in delays in attaining HI approvals.

1.2 Signatory Notification (within Host Institution)

Once the Host Institution is selected at the initial stages of application creation this will allow the Lead Applicant-Researcher 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-Researcher's intention to submit an application to the PQA 2019. The signatory's details are pre-populated in the system so the applicant just needs to click 'NOTIFY' within GEMS. We recommend that you **notify the HI signatory** of your intention to apply as soon as possible in the application process. The signatory will receive an email from GEMS with the name and email details of the Lead Applicant-Researcher and if they have any queries or clarifications they can engage directly to resolve them with the Lead Applicant-Researcher. The HI signatory must confirm their willingness to participate as HI for the application through GEMS and once they do this a PDF of the application will be available for them to review with a view to them ultimately approving the final version for submission to the HRB.

2. Lead Applicants, Co-Applicants and Collaborators details

2.1 Lead Applicant-Researcher's Details

Details are requested about the Lead Applicant-Researcher including their position and status (contract or permanent) and whether they are seeking salary-related costs and their supervisory experience. Please note that a letter of support from the Host Institution must be provided if the Lead Applicant-Researcher is on a contract position.

For Lead Applicant-Researcher holding contract positions, a **Letter of Support** from the Head of School/Research Centre must also be included.

Host Institution Letters of Support must be provided for (1) all Lead Applicant-Researcher in a contract position and (2) Co-Applicants Researchers in a contract position who are seeking their own salary. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre must include the following information; [Host Institution – insert name] which is the host institution of [applicant - insert name] confirms that [applicant - insert name]: (i) holds an employment contract which extends until [insert date] or will be recognized by the host institution upon receipt of the HRB PQA award as a contract researcher; (ii) has an independent office and research space/facilities for which he/she is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise post-graduate students and post-doctorate researchers. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

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

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

Publications and Funding Record
You are asked to include your 10 most **relevant publications** to this application on which you have acted as senior author.

Publications are automatically included in any application created involving the Lead Applicant Researcher. To update this information edit the 'Update CV' section of 'Manage my Details' on GEMS. You can then use the Publication selection tool in the relevant section of the application form to select your 10 most relevant publications for this application.

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

For the purpose of this application form Funding Record details should be added directly on to the application form and will not be pulled through from the 'manage my details' section of GEMS.

Additional evidence of experience and expertise relevant to this application
Lead Applicant-Researcher's may also wish to include any additional experience or expertise that will support their application. For example, previous experience of working in collaboration with knowledge users to produce research or evidence for health, evidence of how their research outcomes have been translated into areas of policy and/or practice or of links with other researchers (including those from other research disciplines), evidence of Patient Public Involvement in research that they have undertaken, recognised contributions to research for national need (if not apparent from other sections), and roles/responsibilities as a constructive and effective change agent. The word limit is **300 words**.

Applicant Team Partnership
You are asked to outline the rationale of the proposed partnership: resarchers, knowledge users and people affected by Parkinson's/their representative. Highlight any linkages between the academic, knowledge user organisations, patient representatives that may already exist. You must provide evidence on how the applicant team worked together to co-develop the research question and process, and how you will work together as equal partners throughout the research process to achieve the objectives of the proposed research. The word limit is **500 words**

2.2 Lead Applicant-Knowledge User Details
Details are requested about the Lead Applicant-Knowledge User including their position and status (contract or permanent) and whether they are seeking release time salary-related costs. Please note that a **Letter of Release-time approval** from the Lead Applicant-Knowledge User organisation must be provided if the Lead Applicant-Knowledge User is requesting salary-related costs.

The Lead Applicant-Researcher's **contact and CV details** (Name, contact information, institution, present position, employment history, profession and membership of professional bodies) are

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

Evidence of expertise and experience in influencing decision-making
A knowledge user is defined as one in a position of authority to influence and/or make decisions about health policy or the delivery of services and that can act to ensure that the findings of the research will be translated to influence decision making and change within their (or other) organisations.

Knowledge users should highlight their previous and current roles in influencing decision making processes within their organization or other relevant organisations. They should also highlight their specific experiences and expertise for the Lead Applicant-Knowledge User role in relation to the proposed research. The word limit is **300 words**.

Additional evidence of experience and expertise relevant to this application
Lead Applicant-Knowledge User's may wish to include any additional experience or expertise that will support the application. For example, you may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health, link, evidence of Patient Public Involvement in your knowledge user role, and roles/responsibilities as a constructive and effective change agent. If you have research expertise / experience you may wish to include relevant outputs such as publications, funding secured or other outputs. The word limit is **800 words**.

2.3 Lead Applicant-PPI Contributor Details

Details are requested about the Lead Applicant-PPI Contributor. **Contact details** (Name, contact information, any further information that you consider relevant such as present position, profession and membership of professional bodies) can be entered in 'manage my details' section of GEMS and are automatically included in any application created involving that individual.

Description of relevant expertise
The Lead-Applicant PPI Contributor should state clearly what their background relevant to this scheme is (e.g. as a person living with Parkinson's, family member, carer, representative of organisation representing Parkinson's patients). Please describe the extent of your experience in relation to Parkinson's, for example as a service user or carer, relevant experience from your personal life, prior experience in PPI or any other useful background information.
The word limit is **400 words**.

PPI contribution to the project
Please describe the PPI contribution to developing this research question, and the PPI plans for the project. Please describe your experience of research to date if any (either on Parkinson's or in other areas). What prior experience (if any) do you have of working with these researchers? What are your plans for collaboration throughout the research process? How much time are you committing to the project?
The word limit is **600 words**.

2.4 Co-Applicants

The Lead Applicant-Researcher can add up to 10 co-applicants to an application by entering their name on GEMS. If the Co-applicant is already registered on GEMS, the system will find them and will allow the Lead Applicant-Researcher to select them. Alternatively, a co-applicant can be added manually by entering their name and email details. GEMS will send them an email with login details for completing the registration process and will inform them that they have been invited by the Lead Applicant to participate on the application as a co-applicant. PPI Participants can register in the same way as Co-Applicants.

Registered Co-applicants can decide whether to accept or reject their participation and consent to the application being submitted jointly in their name. If a co-applicant rejects participation on an application the PI is informed and may revise the application accordingly. Co-applicants which accept to participate in an application will be able to edit the application. The system will flag through a pop-up warning if another user is working on the application form at the same time. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data but it's 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, Co-applicants must also approve the content of the application.

Co-Applicants Contact and CV Details

Each co-applicant can manage their **contact and CV details** (Name, contact information, institution, present position, employment history, profession and membership details of professional bodies) under the 'Manage my Details' section of GEMS and this information will be automatically included in any application that involves this individual.

Co-Applicants will be asked to select whether they are a **Researcher, Knowledge User, or PPI co-applicants** for the purpose of the proposed research.

2.5 Researcher Co-Applicants

Researcher Co-Applicants will be asked to provide additional information including their 5 most **relevant publications,** their **relevant funding record** and their current position and status (contract or permanent) in the application form.

For Researcher Co-Applicants holding contract positions who are seeking their own salary, a **Letter of Support** from the Host Institution must also be included.

Host Institution Letters of Support must be provided for (1) all Lead Applicant-Researchers in a contract position and (2) Researcher Co-Applicants in a contract position who are seeking their own salary. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre must include the following information; [Host Institution – insert name] which is the host institution of [applicant - insert name] confirms that [applicant - insert name]: (i) holds an employment contract which extends until [insert date] or will be recognized by the host institution

upon receipt of the HRB PQA award as a contract researcher; (ii) has an independent office and research space/facilities for which he/she is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise post-graduate students and post-doctorate researchers. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

2.6 Knowledge User Co-Applicants

Knowledge User Co-Applicants will be asked to provide additional information regarding **Evidence of expertise and experience in influencing decision making within knowledge user organisation(s*).*** *A knowledge user is defined as one in a position of authority to influence and/or make decisions about health policy or the delivery of services and that can act to ensure that the findings of the research will be translated to influence decision making and change within their (or other) organisations.*

They will be asked to highlight their previous and current roles in influencing decision making processes within their organization or other relevant organisations. They should also use this space to highlight their specific experiences and expertise for the Knowledge User Co-Applicant role in relation to the proposed research. The word limit is **300 words**.

Knowledge User Co-Applicants will also be asked to provide information regarding **Additional evidence of experience and expertise relevant to this application.** Co-Applicants may wish to include here any additional experience or expertise that will support the application. For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health, evidence of Patient Public Involvement in your knowledge user role, and roles/responsibilities as a constructive and effective change agent. If they have research expertise / experience, Co-Applicants may wish to include relevant outputs such as publications, funding secured or other outputs. The word limit is **800 words**.

Knowledge User Co-Applicants will be asked if they are seeking a release time allowance as part of this application. Release time for knowledge users is a unique feature of this scheme in that it will allow up to €20,000 per year for release time for the knowledge user(s). The €20,000 per year release time funding can be used in full (if required) to fund one knowledge user applicant/co-applicant or it can be allocated between the knowledge user applicant and a number of knowledge user co-applicants if required. **To be eligible that knowledge user(s) must meet all the following criteria.**

- Be a knowledge user applicant/co-applicant on the award whose primary responsibilities/role specification do not include an expectation to engage in research (i.e. as part of their regular employment);
- Have a clear plan setting out the tasks and activities they will be involved in and how this will add value to the overall aims of the project and its application;
- Have secured their organisations approval for the release time on the project that would justify the allowance and have their organisations certify in a **Letter of Release-time approval** that they are/will be engaged in the activities for which the funds have been requested;

- Will be replaced for the period of time spent on the project by another person, i.e. the award will cover the cost of back-fill for that person.

A **letter of Release Time approval support** from the Co-Applicant-Knowledge User organisation must be provided if the Co-Applicant - Knowledge User is requesting Release time costs.

2.7 PPI Co-applicants

PPI Co-Applicants should provide some information regarding their experience and expertise relevant to this application. For example, they may wish to include relevant experience as a service user or carer, relevant experience from their personal lives, prior experience in PPI or any other useful background information. The word limit is **400 words**.

2.8 Collaborators Details

The Lead Applicant-Researcher can add up to 10 collaborators per application. Unlike Co-applicants, the information for Collaborators is not automatically drawn from the 'Manage my Details' section of GEMS but must be entered by the Lead Applicant-Researcher. The Lead Applicant-Researcher 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) (five most relevant publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) relevant to this application where the collaborator has acted as Principal Investigator or Co-Applicant).

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

3. Project Details

3.1 Project Title

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

3.2 Project Duration and Start date

Please indicate the expected length of the proposed project in months (minimum duration of 12 months and maximum duration is 24 months) and the proposed start date. It is expected that the earliest start date will be October 2019.

3.3 Project Lay Summary

You are asked to provide a brief summary of the proposed research including the relevance for people with Parkinson's in Ireland, their families and carers. Summarise the objectives, design, expected outcomes and potential of the findings to translate beyond the research setting.

The lay summary needs to be written as a plain English summary, such that it is clear, easy to understand, and is easily accessible to a broad lay audience. Avoid the use of highly technical terms. This summary may be used when providing information to the public concerning the variety of research funded by the HRB. The word limit is **300 words**.

3.4 Project Abstract

This should be a succinct summary of the proposed research. This structured summary should outline the background to the research, the aims of the work, including the question to be addressed by the research, the plan of investigation and a summary of the potential impact on health and social care policy and/or practice. Ideally it provides a clear synopsis of your proposal and should set the research proposal in context. The word limit is **300 words**.

Please note that this section of the application form will be used as an overall summary, and therefore, should be a stand-alone section. Any abbreviations used elsewhere in the proposal should be defined here.

3.5 Keywords

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

4. Project Description

Please ensure that your application is focused and that sufficient evidence is provided to enable the international peer reviewers and grant selection panel members to reach a considered judgement as to the quality of your research proposal, its scientific merit and the potential impact of the project in an Irish context. Of particular importance is that you clearly highlight the rationale for the proposed research **within the Irish context** and keeping in mind that the reviewers will not be from Ireland you must clearly state the rationale and how the findings of the study will be used to influence decision making in the knowledge user's organisation(s).

The Project Description must include:

- Current knowledge, Background to the area, Relevance and Knowledge Gap
- Overall Aim
- Objectives and Deliverables (including Gantt chart or alternative)
- Research Design and Methodological approach
- Public Involvement in Research
- Gender issues in the research project
- Potential Risks and Ethical Concerns
- Impact Statement
- Knowledge Translation and Dissemination Plan
- Project Management

4.1 Current knowledge, Background to the area, Relevance and Knowledge Gap

Describe the background to the research proposal and detail the size and nature of the issue to be addressed. Include evidence from the literature and give references to any relevant systematic reviews. Where available, include a description of any pilot work, professional and consumer consensus studies already undertaken.

Summarise the need for research in this area, and the rationale for the particular lines of research you plan to pursue. Explain what role people affected by Parkinson's played in identifying the research question and shaping the research.

Clarify the importance of the proposed research for Ireland at a national level and describe the anticipated outputs, outcomes and impact of the proposed research, indicating the anticipated timescale for any proposed benefits to be realised. Provide a clear description of the problem to be addressed and explain why it is important and timely, especially in an Irish context. Be aware that the peer reviewers reading your proposal 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.

Demonstrate how the proposed research will build on existing research to influence the application of the research findings into the Irish healthcare system.

Explain how the research has the potential to address the knowledge gap within healthcare services or policy and how it will accelerate the translation of the findings to enable evidence informed decision making. The word limit is **1200 words**.

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

4.2 Overall Aim

Please state the overall aim of the research project. The awards will provide support for applied research proposals of between 12-24 months duration and where the findings from the research will have a direct impact on the decision making of the knowledge user's organisation/s. The word limit is **100 words.**

4.3 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.

4.4 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, the methods of data collection, measures, instruments and techniques of analysis for quantitative and qualitative designs, outcomes measures and plans for data analysis/data management. Where research involves human participants, please justify any exclusions based on age or sex of participants.

Show how your research design will allow you to answer your research question.
The word limit is **4500 words**

4.5 Public and Patient Involvement in the research project

Please **describe** (i) public involvement to date, (ii) how that has influenced/changed what work has been planned, and (iii) public involvement planned for the duration of the award.
Provide information on the individuals/groups and the ways in which they will be involved. **Where members of the public/patients are involved, they must be compensated for their time and contributions; this should be reflected in the project budget.**
*Please note PPI does **not** include the recruitment of study participants. Whilst this falls under patient-oriented research, it is participation of the public rather than involvement. It also does **not** include work aimed at raising awareness of the public around research, such as media publications of research findings, and outreach activities such as open days in research facilities.*
Useful resources including practical examples of involving members of the public in your research can be found in Appendix II. The word limit is **600 words**.

4.6 Gender issues in the research project

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

- If so, outline how sex and/or gender analysis will be integrated in the design, implementation, evaluation, interpretation and dissemination of the results of the research proposal.
- If not, you must clearly demonstrate why it is not relevant to the research proposal; have you done a literature search to confirm this?

Please see Appendix II for resources on gender and sex considerations in research proposals.
The word limit is **500 words.**

4.7 Potential risks and ethical concerns

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

4.8 Impact statement

Summarise the impact from the proposed research to the knowledge user organisation(s). Include a clear statement of the relevance of the proposed research to the identified priorities in Ireland and the impact that it will have in the short term for people with Parkinson's, their families or carers, or those involved in relevant delivering health and social care services (1-2 years following the end of the award).

This statement should be specific and provide information that the external reviewers will find helpful in assessing the potential impact of the proposed research. Impact statements should be written primarily in plain English, and cover potential impacts in terms of who will benefit from this research as well as how they will benefit. The word limit is **600 words.**

4.9 Knowledge Translation and Dissemination Plan

Please outline the knowledge translation plan including the processes or steps that will be undertaken throughout the period of the award to support the uptake of the research findings to influence health and social care policy and/or practice specific to Parkinson's Disease. The knowledge translation plan should also include plans for the end of grant diffusion and dissemination. It should also detail the management process that will be used to ensure that the knowledge from the research is not just disseminated but is actively translated to influence policy and/or practice.

In addition the research team should detail how they will assess the impact of the project on the knowledge user organisation(s).

This should include the following: how knowledge exchange strategies will be tailored to meet the needs of stakeholders so the results are of maximum utility; and the planned timeframe and forum for implementation (should results be positive). Applicants are expected to identify and demonstrate how the research findings are likely to enable the healthcare services or policy sector to make informed decisions or valuable changes to its practice, expenditure and/or systems in the short term (up to 2 years).

In developing the knowledge translation plan, applicants are advised to consider the following questions:

- What relevant findings will the project have that will ultimately have a substantive and sustainable impact on national health outcomes, practice, programmes and/or policies relevant for Parkinson's Disease?
- To what extent are knowledge users involved from framing the research question and methodology, conducting the research, interpreting the results and informing knowledge translation plans/activities?
- Are knowledge exchange and dissemination activities suitable for its goals and target audiences?

Note: Applicants should ensure knowledge translation and not just dissemination is clearly outlined in this section.

Please note the HRB has a mandatory Open Access publication policy; demonstrate how you plan to make all publications open access. Types of publication routes include [19]:

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

HRB Open Research: rapid open-peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee. (www.hrbopenresearch.org)

Note: applicants are strongly advised to read the Guidance Notes and in particular the assessment criteria that will be used to assess applications. The word limit is **600 words.**

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

4.10 Project Management

Please describe how the research project will be managed. Describe any oversight, advisory or governance structures that are crucial to delivery of the project, including a steering committee or data safety and monitoring committee if applicable. Outline the processes that will be put in place to ensure that the project is well managed, commenting on project management, meetings schedules, financial management etc. The word limit is **600 words.**

A file upload option is available to include an attachment to support your Project Description. A maximum of 5 figures, which can be a combination of images, graphs, tables, scales, instruments or surveys, may be uploaded as a single document on HRB GEMS. They must not be embedded within the text of the Project Description. The maximum size is 2MB.

4.11 FAIR Data Management

Describe the approach to data management that will be taken during and after the project, including who will be responsible for data management and data stewardship. Please consider the FAIR Guiding Principles for scientific data management and stewardship: Findability, Accessibility, Interoperability, and Reusability[20]. Please consider issues such as the types, volume and format of data, and what data will be collected, processed or generated. Consider what metadata and documentation will accompany the data. Will there be a globally resolvable, unique, persistent identifier (such as DOI)? What data quality control measures will be used? Please consider how data will be stored and backed up. How will data security be addressed?

How and when will you share the data? How will you select data for preservation and where data will be preserved long term (e.g. data repository, archive). What methods or software tools will be required to access data? Who will be responsible for data management (e.g. data steward) and the time needed for data management and for making data FAIR (costs may be added under the budget section). Where it is envisaged that a Data Management Plan (DMP) will be created during the project please indicate this, and include delivery of the DMP and any planned revisions within the project deliverables. The word limit is **500 words**

4.11 References

A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of 30 publications. Please enter references in the same format. For example the following format may be used:

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.

5. Details of Research Team

5.1 Lead Applicant-Researcher

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

Outline the role of the Lead Applicant-Researcher in this project on a day-to-day basis including the amount of time to be dedicated to working on this project, either as a percentage or a proportion of a full time equivalent (FTE). The word limit is **250 words**.

5.2 Lead Applicant- Knowledge user

Outline the role of the Knowledge User Principal Investigator in this project on a day-to-day basis including the amount of time to be dedicated to working on this project, either as a percentage or a proportion of a full time equivalent (FTE). The Lead Applicant-Knowledge user must describe how their role and position will enable them to influence change and action arising from the research proposed. The word limit is **250 words.**

5.3 Lead Applicant-PPI Contributor

Outline the role of the PPI Contributor Principal Investigator in this project on a day-to-day basis including the amount of time to be dedicated to working on this project, either as a percentage or a proportion of a full time equivalent (FTE). The Lead Applicant-PPI Contributor must describe how their role and position embeds them throughout the project process, and represents those affected by Parkinson's throughout the research. The word limit is **250 words.**

5.4 Co-Applicant's Role

For each Co-Applicant please outline their role in the project. The word limit is **250 words**.

5.5 Collaborator's Role

For each Collaborator please outline their role in the project. The word limit is **250 words**.

5.6 Personnel

Please give details of all personnel to be funded through this project including the Lead Applicants if relevant. Note that you must justify the nature of all research personnel relative to the scale and complexity of the project. If funding is requested for known personnel, please include the following details: Name, address, present position, academic qualifications and professional qualifications. The word limit is **400 words**.

6. Infrastructure & Support

Infrastructure and Support

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

7. Project Budget

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

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

The following costs can be requested under the PQA budget: Personnel costs, Running costs, FAIR Data management costs, Equipment costs, Dissemination costs and Overhead costs.

Important: The €20,000 per year release time funding for knowledge user applicants and /co-applicants should be detailed under Personnel costs.

Note: You are <u>strongly advised</u> 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 all salaried personnel
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 scales 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. Applicants are advised that public sector pay increases for the period until end of 2020 have been agreed. Please find new pay scales at https://www.iua.ie/research-innovation/researcher-salary-scales/ If your application stretches beyond 2020; please apply a salary contingency of 2.5% p.a. **Note:** The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators.
b) Employer's PRSI	Employer's PRSI contribution is calculated at 10.95% of gross salary in 2019, increasing to 11.05% in 2020.
c) Employer Pension Contribution	Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution. If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health

	Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
2. **Running Costs**	For all costs required to carry out the planned activities including materials and consumables, survey costs, travel for participants, transcription costs and any other relevant costs not covered under the named categories. Costs associated with involving members of the **public or patients** in your research, including costs of the Lead Applicant: PPI Contributor, should be charged to running costs. This might include e.g. participation in Steering Meetings, conducting research, participation in workshops, participation in advisory groups, travel expenses, refreshments etc. All costs must be fully justified. 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.
3. FAIR data management costs	Costs related to data management, FAIRification, storage and archiving of research data in line with best practice of data management and stewardship and the FAIR principles **incurred during the lifetime of the project** should be included.
4. **Equipment**	Funding for small items of suitably justified equipment can be included in this section. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e. overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified. All costs must be inclusive of VAT, where applicable.
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 under knowledge dissemination and exchange activities in the dissemination and knowledge translation plan as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[21]. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary.) Note that meetings between the research team members for purposes of carrying out the research activities should be submitted under running costs.
5. **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 **clinical 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.

8. History of Application and Resources

8.1 Use of resources

Please demonstrate that the resources requested, plus other in-kind resources where applicable, are sufficient to successfully deliver this project on time. Please explain how good use is made of the budget requested, sharing resources where it is appropriate.
The word limit is **200 words**.

8.2 History of this application

Please indicate if you have submitted this, or a similar application, to another HRB scheme or funding body previously. If this application has been submitted elsewhere, please indicate which HRB scheme or funding body, project title, result of submission or when outcome is expected and the amount of award. The word limit is **500 words**.

[21] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-open-access//

8.3 Other funding

Give details of any other financial support available for this or other related projects e.g. existing national or international studies. Indicate project title, funding agency or sponsor, the amount of award and a summary of the project. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review. The word limit is **1000 words**.

9. Ethical Approval

Ethical approval is required for all research work that involves human participants and human material (including tissue).

If ethical approval has already been secured for this grant you will be requested to upload a copy of the relevant approval letter with this application.

If documents are not currently available, they must be sent to the HRB prior to any work commencing where the ethical approval is required.

10. Exclusion of International Peer Reviewers

You are allowed to nominate up to **two individuals that you would exclude as peer reviewers** for your proposal in the PQA international peer-review process. Please refer to HRB Conflict of Interest Policy[22] for further details.

Submission of Applications

The deadline for submission of complete applications is 21 February 2019 at 13.00.

1. After successful validation the Lead Applicant Researcher 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 Researcher 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 Researcher to upload all supporting

[22] http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/conflict-of-interest/

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.

Appendix II: 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.
https://www.cochranelibrary.com/

The Campbell Collaboration: promotes positive social and economic change through the production and use of systematic reviews and other evidence synthesis for evidence-based policy and practice
https://www.campbellcollaboration.org/

The Campbell Collaboration UK & Ireland: hub at Queens University Belfast
https://www.qub.ac.uk/research-centres/CampbellUKIreland/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies
http://www.equator-network.org/resource-centre/library-of-health-research-reporting/

RESEARCH PRIORITIES & PUBLIC INVOLVEMENT IN RESEARCH

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

INVOLVE national standards for Public Involvement
http://www.invo.org.uk/posttypepublication/national-standards-for-public-involvement/

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

Public Involvement Impact Assessment Framework (Assess the impacts of involving members of the public in their research in diverse fields from health care to local history.)
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

GENDER/SEX ISSUES IN RESEARCH

Examples of case studies in Health & Medicine where gender/sex matters in research
http://genderedinnovations.stanford.edu/case-studies-medicine.html

Gender Toolkit in EU-funded research for examples and guidance (health-specific)
https://www.yellowwindow.com/genderinresearch