



JPND Joint Transnational Call on “Multinational research projects on Personalised Medicine for Neurodegenerative Diseases” 2019

Guidance Notes

<u>Key dates & Times</u>	
Call Announcement	7 January 2019
Submission deadline for pre-proposals	12 March 2019 (14:00 GMT)

This document provides additional guidance to researchers based in Ireland applying to this call as part of a transnational consortium. This document must be read in conjunction with the call documents listed in Appendix I, and the FAQ for this call on the HRB website.

1. Introduction

The problem of age-associated neurodegenerative disorders is a growing socio-economic problem in many countries. Over seven million people in Europe suffer from neurodegenerative diseases, yet treatments that prevent or stop the progression of neurodegeneration are still lacking. This places a heavy burden on the individuals with disease, their relatives and society as a whole; a problem that will worsen as the European population ages. Tackling this ‘grand’ challenge is clearly beyond the scope and resources of any one country. To this end the **Health Research Board** is a partner in a member states-led initiative called the EU Joint Programme on Neurodegenerative Disease Research (JPND) (<http://www.neurodegenerationresearch.eu/about/>).

The ultimate goal of JPND is to accelerate progress in understanding the causes of these debilitating conditions, leading to not only early diagnosis and the development of new treatments and prevention, but also the provision of more effective medical and social care to improve the quality of life for patients and care givers. On February 7th 2012 JPND launched their Research Strategy for neurodegenerative diseases detailing priorities for basic, clinical and social and healthcare research. The JPND Research and Innovation Strategy, published in 2012 and updated in 2017, outlines the intention to launch initiatives each year, including Calls for proposals, to address high priority areas in neurodegenerative disease research in line with this Research Strategy.

One of the greatest challenges for neurodegenerative diseases treatment is the deciphering of the large variability – in origins, mechanisms and clinical expression – that these debilitating diseases are characterised by. With this in mind, **JPND has identified a pressing need for investment aimed at enabling research projects on Personalised Medicine**, that may in time bring about the delivery of targeted and timely prevention and therapies for patients of neurodegenerative diseases.

This call, launched in partnership with the European Commission, invites proposals for ambitious, innovative, multinational and multidisciplinary collaborative research projects to change the trajectory of these debilitating diseases through the development of Precision Medicine approaches.

Relating to the targeting of specific elements responsible for pathology in a given individual at a particular point in time, Precision Medicine is an emerging approach for disease prevention, diagnosis and treatment that takes into account individual variability in genes, biological/molecular characteristics, along with environmental and lifestyle factors. For this reason, on January 7th 2019 JPND launched a joint transnational call, to support “Multinational Research Projects on on Personalised Medicine for Neurodegenerative Diseases”

The call will be conducted simultaneously by the participating funding organisations in their respective countries and coordinated centrally, with a single proposal submission and peer review system.

The Health Research Board (HRB) *Strategy 2016 – 2020: Research. Evidence. Action.*¹ launched in January 2016 and highlights three areas of focus that the HRB will engage in over the next four years. The HRB Strategy aims to address major health challenges through support for high-quality, investigator-led, internationally competitive research. HRB will support research that is driven by excellence and originality, with the aim of informing the future development of innovative or novel therapies, treatments, prevention strategies, services and interventions. In line with its strategic objectives, the Health Research Board (HRB) will act as a funding partner in this joint transnational call, and Irish participants in successful consortia will be funded through the HRB, to a maximum of €370,000.

Aim and Scope

The aim of the call is to establish a number of ambitious, innovative, multi-national and multi-disciplinary collaborative research projects that will add value to the respective research areas.

Most patient related research would be impossible without the active involvement of patients. Thus, JPND has determined that Patient and Public Involvement should be an integrated part of the implementation of its Research and Innovation Strategy. Proposals to be funded under this call will therefore need adequately to involve patients, carers and the public. Consortia are expected to make every effort to include approaches that involve these groups, where appropriate, at each stage of the research process including the preparation of the application (see the JPND website for further information). In the

¹ <http://www.hrb.ie/publications/hrb-publication/publications//702/>

application it must be described in which step of the research process patients, their relatives or carers will be involved, from where they will be recruited and which roles they would play. Reasons must be given if such an approach is not taken.

Proposals submitted under this call will have to include one or several of the research areas listed below:

Diagnosis, by integrating the validation and harmonised use of biomarkers, deep analysis of data from noninvasive imaging (with associated development of interoperable methodologies and protocols), high throughput “omics” approaches and big data analyses, recognising the critical importance of promoting reproducibility through data standardisation and quality control of data and biomarker stability at all stages of work. Where appropriate, studies should include head to head comparisons and benchmarking of assays/methods. This will prepare the ground for pooling and sharing of data as well as cross-initiative data exchange, e.g. by establishing guidelines for data access and management or by establishing or refining core common formats and requirements for data. This will allow a better classification and segregation of disease diagnoses for more targeted care and will open up new insights for future clinical studies.

Prevention, through the identification of predictive, translatable biomarkers to study the efficacy of novel treatments and to stratify populations for preventive interventions. Biomarkers that integrate real-life measures based on digital technology and that permit the stratification of risk by gender or ethnicity are welcomed. This approach will allow the assessment of the impact of co-morbidities (vascular disease, inflammation, and metabolic disorders), the appreciation of cross-disease commonalities, and the identification of people who would benefit from preventive strategies and treatments. Integrating digital technologies within research on neurodegenerative diseases, establishing better connections between long term observational cohorts and clinical trials as well as an enhanced understanding and modelling of healthy ageing are crucial. For this, also existing longitudinal cohort studies (e.g. studies set up initially for cardiovascular or metabolic research purposes) that have data sets that are relevant for the study of neurodegenerative disease should be made use of. The aim is to postpone the onset and slow the progression of these diseases, thus reducing de facto their prevalence and population impact.

Care, based upon an evidence-based approach to social and health care systems, addressing all aspects of these chronic diseases including any comorbidity, spanning care provision, diagnostic disclosure, palliative care and health economic studies to guide improved care in a more efficient way. Through enhancing understanding of the large variability in the origins, mechanisms and clinical expression at the patient level, Precision Medicine opens up new and important opportunities for optimising care outcomes. Maximising these opportunities will require the introduction of new medical models that successfully incorporate molecular profiling, medical imaging, lifestyle data and other data. Better use of real world

data and establishing common standards for the content and quality of this data type is urgently needed, as well as improved approaches towards including patients and other members of the public and health & social care elements. The communication gap between the neurodegenerative research community and healthcare providers as well as with patients, needs to be bridged.

Full details of the scope of the call, including areas excluded from this call, should be reviewed carefully in the **Call Text** which can be accessed at this link: <http://www.neurodegenerationresearch.eu/initiatives/annual-calls-for-proposals/open-calls/personalised-medicine-2019/>

2. Eligibility criteria

2.1 Eligibility requirements for the Project Team

Only transnational projects will be funded.

In summary

- Each proposal must involve a minimum of three and a maximum of six regular partners, including the coordinator, from at least three different countries that are participating in this call.
- If the proposal involves at least one regular partner from an underrepresented European country (Czech Republic, Hungary, Latvia, Poland, Romania, Slovenia, Turkey), the maximum number of regular partners is extended to seven partners.
- No more than two regular partners from the same country are allowed to join a proposal.
- In addition, external collaborators (e.g., research groups from countries that are not participating in this call or research groups that are from countries participating in this call but do not apply for funding) may participate in proposals. External collaborators must secure their own funding.
- Whilst proposals are to be submitted jointly by research groups from different countries, individual regular partners will be funded by the corresponding funding organisation of their country participating in this call. In consequence, eligibility for funding is decided by the respective funding organisations and details of what may or may not be funded are subject to the specific regulations of these funding organisations and thus may vary.
- Individual budget restrictions will apply for each country and/or funding organisation: coordinators should pay close attention to these.

Up to date information on which countries are participating in this call, together with country-specific specific eligibility requirements, is available on the JPND website (<http://www.neurodegenerationresearch.eu/initiatives/annual-calls-for-proposals/open-calls/personalised-medicine-2019/>).

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

2.2. Eligibility of researchers based in Ireland

All proposals with researchers from recognised host institutions in Ireland will be subject to a HRB eligibility check following submission to the centrally coordinated peer review to ensure:

1. The investigator(s) from Ireland is from a recognized host institution. The Host Institution for the award is the body in charge of the financial and administrative co-ordination of the Irish component of the research project receiving a research grant from the HRB. A Host Institution must be a recognised research organisation in the Republic of Ireland. **Queries regarding eligibility of Host Institutions should be directed to HRB prior to submission.** For further information see: <http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/>.
2. The PI (group leader) named on the award holds a post (permanent or a contract that covers the duration of the award) in a recognised research institution in the Republic of Ireland (the “Host Institution”) as an independent investigator, **or** is a contract researcher recognised by the Host 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** is an individual who will be recognised by the Host Institution upon receipt of the HRB award as a contract researcher as defined above. The Principal Investigator does not necessarily need to be employed by the Host Institution at the time of the application submission.

3. The PI has demonstrated research independence through securing at least one peer-reviewed, independent research grant as a Principal Investigator or as Co-Investigator and is a senior author (first, last or corresponding or in those fields where alphabetic order authorship is the norm, joint author) in peer-reviewed scientific journals.
4. The PI is not requesting their own salary
5. Any named co-applicants are not requesting their own salary
6. The Irish component of the budget for the project does not exceed €370k (including overheads and pension contributions)
7. Only eligible costs have been included:
 - Salary-related costs
 - Small equipment costs (max €10,000)
 - Travel
 - Direct running costs
 - Dissemination and knowledge exchange costs
 - Overheads
8. The proposed work fits the scope of the call

Any queries on eligibility should be raised with the HRB well in advance of the call deadline.

3. Funding

The total fund for this call is €24m (for all participating countries). It is anticipated that a number of projects will be funded. Whilst joint applications will be submitted involving groups from different countries, individual research groups in successful projects will be funded by the individual JPND funding organisation(s) within their country. The maximum amount that funders in each participating country will contribute to their successful applicants can be found in documents on the following webpage: <http://www.neurodegenerationresearch.eu/initiatives/annual-calls-for-proposals/open-calls/personalised-medicine-2019/> .

For successful bids involving applicants based in recognized host institutions in Ireland, the total available for the research component carried out in Ireland will be a maximum of €370,000 over 36 months (inclusive of overheads and pension contributions). For applicants in Ireland the award will cover the costs of salary-related costs, small equipment costs, travel, direct running costs, knowledge and dissemination costs and overheads.

4. Application process

There will be a **two-stage** procedure for joint applications: pre-proposals and invited full proposals. In each case, a single proposal document (in English) shall be prepared by the partners of a joint transnational proposal, and must be submitted to the Joint Call Secretariat by the coordinator. Each transnational project team submitting a proposal must nominate one PI to act as coordinator. The coordinator will submit a **single application** via the electronic submission system on the following site: <https://ptoutline.eu/app/jpnd2019> . A **proposal template** must be used when submitting the application. This proposal template can be downloaded from the JPND website, along with the **call text** (detailing the aim and scope of the call, eligibility and submission details, the evaluation process and assessment criteria, reporting requirements), **pre-proposal guidelines** and **country-specific requirements**, (<http://www.neurodegenerationresearch.eu/initiatives/annual-calls-for-proposals/open-calls/personalised-medicine-2019/>). *These documents **must be consulted** in addition to the HRB Guidance Notes and HRB Frequently Asked Questions documents on this page.*

Eligible pre-proposals will be reviewed via a written (remote) peer review process. Based on the scores in the written reviews a ranking list will be set up. By mid May 2019, the coordinators of the top-ranked proposals will be invited by the Joint Call Secretariat to submit a **full proposal** no later than June 25, 2019 (14:00 GMT).

Full details on the evaluation process and assessment criteria are contained within the **call text**.

Applicants from Ireland in consortia invited to submit a full application will be required to provide additional information to the HRB at the time of the full application submission deadline. This will include justification for their requested budget, and clarification on deliverables assigned to the partner from Ireland. A template requesting the information required from applicants from Ireland will be provided by the HRB.

It is the responsibility of the applicants in each country to ensure that their host institution(s) have reviewed and approved the budget prior to submission. Please allow sufficient time for these additional processes. Any late applications will be rejected.

5. Timeframe

The expected timeframe for this call for proposal is as follows:

7 January 2019	Publication of the JPND Joint Transnational Call
12 March 2019	Deadline (pre proposals)
8 May 2019	Coordinators invited to submit full proposals
25 June 2019	Submission deadline for full proposals
July-September 2019	Peer Review Procedure
October 2019	Final funding decisions at national/regional level
Late 2018/Early 2019	Start of funding

6. Contacts for further information

For **general enquiries** on this call, the Joint Call Secretariat for this call can be contacted at:

Dr. Olaf Krüger

Phone: +49 228-3821-2111

E-mail: olaf.krueger@dlr.de

Dr. Sabrina Voß

Phone: +49-228-3821-2111

E-mail: Sabrina.voss@DLR.de

For specific enquiries from applicants **from Ireland** to this call, contact:

Dr Tonya Moloney

HRB Postdoc Fellow, Research Strategy and Funding

Health Research Board

Tel: 01 2345 256

Mail: tmoloney@hrb.ie

The HRB reserves the right to reject any application that does not meet the terms of this call. The decision of the HRB Board in respect of any grant application is final and cannot be appealed or reviewed. In view of the overwhelming evidence that both active and passive smoking of tobacco are injurious to health, the HRB is unwilling to fund applications from individuals applying for, holding, or employed under a research grant from the tobacco industry. The HRB cannot fund research using human embryonic stem cells or tissues, or 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.

Appendix I

Call documents and Useful links

<p>Main website including</p> <ul style="list-style-type: none"> • Call text • Proposal template (submissions must use this template) • Contact details for Call Secretariat 	<p>http://www.neurodegenerationresearch.eu/initiatives/annual-calls-for-proposals/open-calls/personalised-medicine-2019/</p>
<p>Website for proposal submission</p>	<p>https://ptoutline.eu/app/jpnd2019</p>
<p>Country-specific information (including funding available per funding organization and specific eligibility criteria)</p>	<p>http://www.neurodegenerationresearch.eu/initiatives/annual-calls-for-proposals/open-calls/personalised-medicine-2019/country-specific-details/</p>
<p>Website giving background to JPND initiative</p>	<p>http://www.neurodegenerationresearch.eu/about/</p>