



**Joint Transnational Call for Proposals 2019
“Personalised Medicine: Multidisciplinary Research Towards
Implementation”**

HRB Guidance Notes

<u>Key dates & Times</u>	
Call Announcement	9 February 2019
Submission deadline for pre proposals	7 March 2019 (16:00 GMT)
Submission deadline for <u>invited</u> full proposals	17 June 2019 (16:00 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 Health Research Board is currently engaged in the International Consortium for Personalised Medicine (ICPerMed)¹. This initiative brings together over 31 European and international partners representing ministries, funding agencies and the European Commission (EC). Together, they work on coordinating and fostering research to develop and evaluate personalised medicine (PM) approaches. The work of ICPerMed is based on the definition of personalised medicine given in the European Council Conclusion on personalised medicine for patients (2015/C 421/03)².

It states “[...] that it is widely understood that personalised medicine refers to a **medical model** using characterisation of individuals’ phenotypes and genotypes (e.g. **molecular profiling, medical imaging, lifestyle data**) for tailoring the right **therapeutic strategy** for the right person at the right time, and/or to determine the **predisposition to disease** and/or to deliver timely and targeted prevention.”

ICPerMed developed an Action Plan during 2016, which contains a set of actionable research and support activities for ICPerMed members and other interested funders over the following two years. One such action is the launch of the European Research Area Network for personalised medicine (ERA-PerMed)³, currently supported by 32 partners of 23 countries and co-funded by the European Commission. The aim of ERA-PerMed is to align national research strategies, promote excellence, reinforce the competitiveness of European players in PM, and enhance European collaboration with non-EU countries. In January 2019 the members of ERA-PerMed launched the second Joint Transnational Call for collaborative innovative research projects in Personalised Medicine (PM). HRB is supporting participation of researchers from Ireland within this call.

¹ <http://www.icpermed.eu/index.php>

² [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217(01)&from=EN)

³ <http://www.erapermed.eu/>

2. Call details

2.1 Aim

With its second transnational call (non-cofunded by the EC), ERA PerMed fosters research and innovation activities that build close linkages between basic biomedical research, clinical research, physical sciences and bioengineering, bioinformatics and biostatistics, epidemiology, socio-economic research, as well as research on the integration of PM into clinical practice and on ethical, legal and social implications across the participating countries and beyond. This implies a wide range of multidisciplinary activities brought together by different stakeholders from academia (e.g. universities and research institutions), clinics (e.g. clinical laboratories, medical professionals), industry (e.g. pharmaceutical industry, biotechnology companies, information technology companies including Health Information Technology – HIT), policy makers, regulatory/health technology assessment (HTA) agencies and patients/patient organisations.

The overarching goal is to improve disease management, based on broader and more efficiently elaborated patient stratification, diagnostics and tailored treatment protocols, and disease prevention. The project development should include early involvement of regulatory authorities as well as close interaction with the different key players along the value chain to bridge the gap between first discoveries or inventions until market access. Proposals submitted under this call are expected to demonstrate the applicability of project outcomes to clinical practice. The clinical relevance of the suggested PM approach needs to be convincingly shown. Moreover, proposals are expected to include research on ethical, legal and socio-economic implications, including health economics and regulation, and/or research on optimisation of health care systems.

2.2. Objectives

The overall objectives of the Joint Transnational Call 2019 are:

- To support **translational research projects** in the field of Personalised Medicine;
- To encourage and enable **interdisciplinary collaborations towards implementation of PM**, combining pre-clinical and/or clinical research with bio-informatics components and research on relevant ethical, legal and social aspects and/or research on the optimisation of health care systems;
- To encourage **collaboration between academia** (research teams from universities, higher education institutions, public research institutions), **clinical/public health research** (research teams from hospital/ public health, health care settings and other health care organisations),

private partners e.g. **SMEs** (small and medium-sized enterprises) as well as policy makers, regulatory/HTA agencies and patient organisations.

2.3 Scope

Briefly, the JTC2019 of ERA PerMed comprises three Research Areas:

Research area 1 “Translating Basic to Clinical Research and Beyond”	Research area 2 “Integrating Big Data and ICT Solutions”	Research area 3 “Research towards Responsible Implementation in Health Care”
Module 1A: Pre-clinical Research	Module 2A: Data and ICT – Enabling Technology	Module 3A: Optimising Health Care System
Module 1B: Clinical Research	Module 2B: Data and ICT - Towards Application in Health Care	Module 3B: Ethical, Legal and Social Aspects

Each project proposal **MUST** address **at least one module of Research Area 3** and **at least one module of Research Area 1 or 2**. The coherent integration and combination of the different Research Areas and Modules in the proposals is part of the evaluation process. **The call text gives details of what research areas can be supported by funders in each jurisdiction.**

Please review the published text for full details of the scope of the call on <http://www.erapermed.eu/joint-transnational-call-2019/>

2. Eligibility criteria

2.1 Call eligibility requirements for the Project Team

- Only transnational projects will be funded.
- **Each consortium submitting a proposal must involve at least three partners eligible for funding coming from three different countries whose funders participate in the call** (see list above). All three legal entities must be independent of each other.
- The **project coordinator must be eligible to be funded** by his/her regional/national participating funding organisation.
- **The maximum number of partners per project at the pre-proposal stage is six. At the full-proposal stage, the consortium may be expanded to up to seven partners in total only by inclusion of a partner from an underrepresented country.** A list of underrepresented countries will be provided to the coordinators invited to submit full-proposals.

- **Within one consortium, no more than two partners from the same country participating in the call will be accepted, including those partners with their own funding.** For some funding agencies the maximum number of eligible partners that can be funded in one project is limited to one (see also “Guidelines for Applicants” for individual funding rules).
- Partners not eligible for funding by one of the organisations participating in this JTC (e.g. from non-funding countries or not fundable according to the regional/national regulations of the participating funding organisations) may participate in projects if they are able to secure their own funding. **No more than one partner with its own funding is allowed** in consortia with at least 3 partners eligible for funding.

Full information on eligibility requirements, up to date information on which countries are participating in this call, together with country-specific specific eligibility requirements, is available in the Guidelines for applicants on the ERAPerMed website: <http://www.erapermed.eu/joint-transnational-call-2019/>

Joint transnational research proposals may be submitted by research groups working in universities (or other higher education institutions), non-university public research institutes, hospitals and other health care settings, as well as commercial companies, in particular small and medium-size enterprises. Participation of clinicians (e.g. medical doctors, nurses) in the research teams is encouraged. The eligibility of the afore-mentioned institutions, together with details of eligible costs (personnel, material, consumables, equipment, travel money, etc.), are subject to the individual administrative requirements of individual funding organisations and may therefore vary from country to country.

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, clearly justified)

- 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

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 participating ERAPerMed 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 the call text http://www.erapermed.eu/wp-content/uploads/2019/01/ERA-PerMed_2019_Call_text_F.pdf

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/erapermed2019>. Research project consortia who intend to submit a transnational proposal should register on that site as soon as possible by clicking on “sign up” and following further instructions. A **pre-proposal submission form** must be used when submitting the application. This proposal template can be downloaded here [Page 7 of 10](http://www.erapermed.eu/joint-</p></div><div data-bbox=)

[transnational-call-2019/](#) , along with the **call text** on the same page (detailing the aim and scope of the call, eligibility and submission details, the evaluation process and assessment criteria, reporting requirements), and **country-specific requirements**. *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. The reviewers will assess the pre-proposals and complete a written evaluation form with scores and comments for each criterion. The Call Steering Committee members (funders) will meet to decide which proposals will be invited for the full-proposal submission based on the reviewers' recommendations and to ensure a reasonable balance of requested and available national/regional budgets. 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 17, 2019.

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:

9 January 2019	Publication of the ERAPerMed Joint Transnational Call
7 March 2019	Deadline (pre proposals)
13 May 2019 (est.)	Coordinators invited to submit full proposals

17 June 2019	Submission deadline for full proposals
July-September 2019	Peer Review Procedure
September 2019	Recommendations from Peer Review Panel
October 2019	Final funding decision at national/regional level
January-July 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:

Monika Frenzel

50 Avenue Daumesnil, 75012 Paris, FRANCE

Tel: +33 (0) 1 73 54 83 32

Mail: ERAPerMed@agencerecherche.fr

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 • Guidelines for Applicants (including country-specific eligibility requirements) • Proposal template (submissions must use this template) • FAQ • Contact details for Call Secretariat 	<p>http://www.era-permed.eu/joint-transnational-call-2019/</p>
<p>Website for proposal submission</p>	<p>https://ptoutline.eu/app/era-permed2019</p>
<p>IC PerMed website</p> <p>IC PerMed Partnering tool</p>	<p>http://www.icpermed.eu/index.php</p> <p>https://partnering.pt-dlr.de/ICPerMed</p>