

# Collaborative Doctoral Awards in Patient-focused Research (CDA) 2021

Building capacity to drive patient-focused research

Guidance Notes		
Key Dates & Times		
Pre-Application Open	28 September 2020	
Pre-Application Deadline	17 December 2020	
Outcome of Pre-Application stage and Invitation to Full Application stage	Late February 2021	
Full Application closes	Mid-May 2021	

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (<u>https://grants.hrb.ie</u>), and this system will close automatically at the stated deadline according to the timeline listed above. Applicants are strongly recommended to read the 'Detailed guidance notes for applicants', appended to this document prior to completing the application form.



# Collaborative Doctoral Awards in Patient-focused Research (CDA) 2021

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# **Collaborative Doctoral Awards (CDA) in Patient-focused Research**

# Building capacity to drive patient-focused research

### **Guidance Notes**

### 1. Overview

The Collaborative Doctoral Awards will support excellent doctoral training programmes for future health researchers in the conduct of patient-focused research, which will ensure the expertise to advance, apply and transfer knowledge from research into clinical application. Ultimately, a cadre of health researchers trained in this way will create tangible impacts on health and patient care.

Each Collaborative Doctoral Award is developed and directed by a leadership team of established investigators. Each award will provide funding to a maximum value of €1.2m (excluding overheads) for five years which will support the training and the research projects of a cohort of four or five PhD candidates for four years on the island of Ireland.

This initiative aims to attract and train to doctoral level multidisciplinary cohorts of researchers, which include both health and care practitioners<sup>1</sup> and academic researchers, from different disciplines (e.g. health economics, bioinformatics, biostatistics, epidemiology, etc.) as relevant to the objectives of the call and the overarching thematic area of the overall programme.

It is envisaged that three awards will be made in the 2021 round.

# 2. Introduction

The HRB Strategy 2016-2020 *Research. Evidence. Action.* highlighted the importance of training, supporting and developing a wide range of researchers from different disciplines and professions along the journey from doctoral training to leadership in health research. The new HRB strategy 2021-2030 corroborates this key objective, by emphasising the importance of supporting and attracting talented health researchers, at all career stages across health and care practice and academia, to build high-functioning research networks and

<sup>&</sup>lt;sup>1</sup> Please note that although medical doctors are not excluded by this training initiative, given the HRB/Wellcome investment on the ICAT programme, a limit of one medical doctor per cohort will be applied unless a very strong case can be made, for example in the case of general practitioners. The CDA awards aim to attract and train a variety of other health and care professions (e.g. nurses and midwives, dentists, pharmacists and allied health professions).

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to sustain successful research based careers that benefit Ireland. One key initiative in line with this objective is to support structured, mentored and cohort-based programmes to train talented individuals at PhD level in order to increase the number of highly skilled researchers who will support and drive patient-focused research in Ireland. These programmes also aim to support the HRB investment of approximately €100M into clinical research and trials infrastructure in Ireland over the last 15 years. These awards will train future researchers in a broad range of expertise needed in the clinical research environment and they will build future capability and capacity in the Irish system to the benefit of patients, the health system and the economy.



Figure 1 - HRB research infrastructure and support for patient-focused research in Ireland

In line with the objective of the HRB Strategy 2021-2030 to "Build a strong and supportive environment for health research in Ireland", the HRB is now inviting applications for the third round of Collaborative Doctoral Awards in Patient-focused Research. In the previous two rounds of this scheme seven awards were made supporting 27 PhD candidates.

# 3. Aims and objectives

The overarching aim of this call is to support excellent doctoral training programmes for a cohort of individuals including those from academic health-related disciplines and particularly those from health and care practice, such as medics<sup>2</sup>, nurses and midwives, pharmacists, dentists and allied health professionals, in the conduct of patient-focused research. This will create expertise, within this mixed cohort, to advance, apply and transfer knowledge from research into impacts on patient health and patient care.

The main objectives of the scheme are:

- 1. To provide individuals with research and professional expertise, competencies and experience to embark in different career roles in the health sector;
- 2. To build capacity among health care professionals and other health-related disciplines by increasing the number of highly skilled researchers who will lead and support patient-focused research and/or translate the findings for a greater impact on patient health;
- 3. To attract and train people, currently working in a healthcare setting, to doctoral level, resulting in better integration between research and health care, improved quality of care and outcomes and a more attractive work environment;
- 4. To increase and/or strengthen cross-sectoral and cross disciplinary collaborations among investigators, experts and stakeholders aimed at addressing important health challenges at national and/or international level in the context of patient-focused research.

# 4. Summary of revisions to the 2021 round

### 4.1 The Leadership Team

Each programme will be directed by a <u>leadership team</u> rather than one Director with the option to include a Co-Director. The leadership team will have two or three members in total, each of whom will hold <u>equal co-Directorship</u> of the Doctoral Programme. The team members must span a breadth of disciplines and professions with skills and expertise which complement one another in order to together lead the scientific and technical direction of the overall doctoral programme. For application purposes there will be one Lead Applicant and one or two Co-Leads.

The Lead Applicant must be from a Host Institution in the Republic of Ireland and the Co-Lead(s) can be from the same Institution or be based in different institutions <u>on the island of Ireland</u>.

Directors or Co-Directors of a CDA Programme awarded in 2018 or 2019 <u>will not be eligible</u> to apply as members of a leadership team in the 2021 round of the call.

### 4.2 PhD Candidates

The leadership team can apply for four or five PhD candidates, a minority of whom may be registered in the North of Ireland for their PhD. However, a majority of PhD candidates must be registered in the Republic of Ireland, meaning that at least three must be registered in Rol institutions.

<sup>&</sup>lt;sup>2</sup> Please note that although medical doctors are not excluded by this training initiative, given the HRB/Wellcome investment on the ICAT programme, a limit of one medical doctor per cohort will be applied unless a very strong case can be made, for example in the case of general practitioners. The CDA awards aim to attract and train a variety of other health and care professions (e.g. nurses and midwives, dentists, pharmacists and allied health professions).

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#### 4.3 Review Process

The following two steps have been introduced into the review process for this CDA round:

- At full application stage (by invitation only) <u>two public reviewers</u> will be invited by the HRB, in addition to international peer-reviewers, to review each application. Public reviewers will only assess the quality of PPI in the proposal and they will provide comments and a rating but not a score.
- An Applicant Response phase will now be incorporated into the review process. This will allow the leadership team to respond in writing to the peer and public review comments associated with their application. It will give an opportunity to the Lead Applicant team, with the input of the wider consortium, to address and clarify any items raised by the reviewers, prior to their interview with the review Panel.

#### 4.3 Panel assessment criteria

At Full Application stage, the <u>five</u> assessment criteria for the Panel review have been grouped into <u>three</u> criteria in line with the pre-application stage.

#### 1. The Consortium

- a. The leadership team;
- b. The consortium: breadth of expertise, skillset, appropriate PPI and other stakeholders' participation;

#### 2. The Research Programme

- a. The likelihood and potential of the programme to advance and translate patient-focused research findings, with impact, to health and patient care;
- b. The quality and coherence of the research projects within the overarching thematic area (including research design and methodologies, feasibility and appropriateness to doctoral training);

#### 3. The Programme Training and Governance

- a. The quality and coherence of the training framework;
- b. Programme management, oversight and governance.

#### 4.4 Overheads

The overhead contribution is excluded from the application budget to avoid any distortion of direct costs available between different types of research. Different overhead rates apply to laboratory-based or clinical research (30 percent of total direct modified costs [TDMC]) and desk-based research (25 percent of TDMC). Please note TDMC excludes student fees and equipment.

# 5. Scope

Current and future health challenges and particularly the application and translation of evidence towards more tangible impacts needs the talent, expertise and ingenuity of a wide range of people from different disciplines and professions including health and care professionals, scientists, epidemiologists, health economists, biostatisticians, health informaticians and others working in collaboration with key stakeholders (e.g. patients, carers, clinical care-decision makers, health managers, etc.).

Each award will support a newly formed or an existing consortium of collaborative, cross-disciplinary and crosssectoral partners, including from overseas and industry where relevant, consisting of academics and health and care practitioners from any healthcare setting and other experts as relevant to the training and research objectives of the programme. Each consortium must have strong PPI and other relevant stakeholder participation. This is in line with the HRB's leading role in promoting and developing initiatives aimed at strengthening the involvement of the public and patients in health research in Ireland.

The concept arising from such consortia creates a whole that is greater than the sum of separate activities.

Each consortium should propose a coherent doctoral training and research programme addressing an overarching thematic area relevant to improving health and patient care within the definition of "patient-focused research". The overarching research thematic area will be assessed in terms of **the relevance** to:

(1) Current and future main health challenges globally and/or nationally, e.g. as highlighted in national and/or international reports/literature, and

(2) The need at national or international level to train individuals in that particular thematic area, methodological approach and/or discipline/profession.

The research programme should support several rigorous research projects of high quality. Whilst each PhD candidate needs to have an **individually identifiable** research project that will satisfy requirements for a PhD thesis, the coherence and interrelation of the different projects within the Programme should be clearly explained. However, research projects should not have interdependency of research outputs amongst them due to the high risk this creates for the dependant PhD candidate. Please note this is a doctoral training programme award and <u>not</u> a programmatic research award.

### For the purpose of this training initiative patient-focused research is defined as

"Research conducted on humans with the goal to improve health and patient care by advancing our knowledge of the efficacy of medications, devices, diagnosis, prevention and treatments and by accelerating the transfer and application of research findings and evidence into effective applications in a real-world healthcare/clinical setting. Research should focus on clinical questions and may span all professions with direct contact with healthy volunteers and/or patients. Applications should focus on T1 and T2 and towards T3 in Figure 2 below.

Applications focussing predominately on research methods in clinical research (including methods specific to healthcare interventions) are also eligible due to the need to build capacity and expertise in this area in Ireland.

Applications may incorporate some components of health services research and/or population health research as relevant to the patient-focused research question to be addressed. However, the centre of gravity of the research projects, capacity building and costs must be predominately weighted towards clinical and patient-focused approaches. Applications will otherwise be ineligible in terms of the scope of this call.



Figure 2 – Health Research translational continuum<sup>3</sup>

The award will not fund:

- Research involving basic biomedical research (T0 in Figure 2)
- Research involving cell lines, animals or their tissues (T0 in Figure 2)
- Research involving pre-clinical models and any pre-clinical studies (T0 in Figure 2)
- Applications proposing a research programme with an interphase between clinical and health service research (HSR) and/or population health research (PHR) where the center of gravity is on HSR and/or PHR. Small components of HSR and/or PHR can be part of the overall patient-focused research programme.
- Applications which are solely literature reviews, audits, surveys, needs assessments or technology development (although these elements may be part of an integrated research study)
- Applications which are solely **or** predominately developing the infrastructure for biobanking, databases or patient registers without a predominant research element
- Applications which are solely **or** predominately health service developments without a predominant research element. The HRB will not fund the cost of providing the service itself, only the research element
- 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

<sup>&</sup>lt;sup>3</sup> From the Centre for Paediatric Clinical Effectiveness in the Children's Hospital Philadelphia <u>http://cpce.research.chop.edu/research-methods-approaches/translational-research</u>

• Applications from individuals applying for, holding, or employed under a research grant from the Tobacco industry.

# 6. Funding and Duration

Each award will have a maximum value of **€1.2m excluding overheads**. Each award will have an overall duration of up to **five years.** This period includes:

- Up to six months before the candidates start to provide time up front for starting the coordination of the training programme and the open and competitive selection of the PhD candidates;
- Four-year support for the PhD candidates and the research and training programme;
- Up to six months' time at the end of the programme for dissemination of the research undertaken during the award. During this period PhD candidates' stipend or salary will typically not be paid.

There is flexibility regarding the choice between stipend or salary contribution for the PhD candidates depending on whether they are from health-related disciplines or from the health and care professions. It will be up to the consortium to justify the case within the funding portfolio. An award will support **either four or five PhD candidates**.

**Note:** The HRB welcomes leveraged funding to this programme to support additional PhD candidates in the cohort or additional funding for the conduct of the overall programme.

Each award will offer:

- ✓ Support for each PhD candidate, depending on their educational background, professional experience and career stage, with either
  - A contribution to gross salary costs (inclusive of employee's pension contribution) up to a maximum amount of Level 3, Point 1 of the most up to date IUA scale for PhD candidates who are health and care practitioners;

Or

- A student stipend of €18,000 for PhD candidates from health sciences disciplines;
- ✓ PhD student fees at EU level only;
- ✓ Contribution to research running costs;
- ✓ Contribution to training and travel (including placements/secondments);
- ✓ Contribution to knowledge exchange and dissemination;
- $\checkmark$  Contribution to administrative and programme management costs.

<u>At contract stage</u> an overhead contribution of 30% of the Total Direct Modified Costs (TDMC) of the full award for clinically based research or 25% of the TDMC for desk-based research will be also calculated. **This will not be included in the budget at the time of application.** 

The maximum value of the award inclusive of overheads is in the region of €1.5M.

Please note that each PhD candidate will need to be registered at a higher education institution on the <u>island</u> <u>of Ireland</u> for their PhD degree. However, a majority of PhD candidates must be registered in the Republic of Ireland, meaning that at least three must be registered in Rol institutions.

# 7. The Consortium

Each award must have a Leadership Team which will include a Lead Applicant and **one or two other individuals** (**Co-Lead Applicants** for the purpose of the application process). The members of the leadership team will hold <u>equal Co-Directorship</u> of the Doctoral Programme. The team members must span a breadth of disciplines and professions with skills and expertise which complement one another in order to together lead the scientific and technical direction of the overall doctoral programme The Leadership team has the primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of the HRB. The Lead Applicant must be from a Host Institution in the Republic of Ireland and the Co-Lead(s) can be from the same Institution or be based in different HRB approved Host Institutions on the island of Ireland.

The team will lead a consortium involving different <u>Partners</u> such as researchers either as academics or health and care practitioners; health and care practitioners – in practice only; Public and Patient Involvement (PPI) contributors; knowledge users; stakeholders from private sectors and/or other stakeholders or experts. Together, these partners will bring the relevant resources, knowledge and expertise to the PhD training experience.

Each partner may be "**core**" (equivalent to co-applicants in other HRB applications) or "**associated**" (equivalent to collaborators in other grant applications) depending on their role in the overall programme, e.g. leadership in training and education, programme coordination, research and thesis supervision, access to patients, mentoring, provision of courses/modules, technical and methodological training and support, workshops, national/international placements, networking activities/events, etc. Core and/or Associated Partners may be internationally based.

The consortium must

- > Contain the necessary **breadth and depth** of research and/or professional expertise
- Have appropriate cross-disciplinary and/or cross-border and/or inter-sectoral approaches to break down the discipline, professional and sectorial barriers in research, preferably including international collaborations.
- Show a strong public and/or patient and/or other relevant stakeholder involvement.

The overall objectives of each consortium are to:

- Provide a structured and mentored doctoral education to one cohort of four or five PhD candidates, who must be selected by an open and competitive recruitment process;
- Attract individuals from different educational backgrounds/disciplines and professions to be trained together (e.g. health and social care professionals, scientists, social scientists, health informatics, biostatisticians, social scientists, etc.). Please note that given the training opportunities for medics under the ICAT programme, participation of medics should typically be limited to one per cohort. If more than one medic is proposed (for example in the case of general practitioners) a very strong case must be made;
- Provide a coherent research programme in a specific thematic area in patient-focused research. The theme should focus on an issue in healthcare, not on a type of research methodology;
- Equip the PhD candidates with skills, competencies and experiences leading to readiness for successful careers in the health and/or academic sector. Graduates should be prepared for academic, non-academic or dual roles.

### 7.1 Leadership Team Eligibility

Each leadership team must have a **Lead Applicant** who will serve as the **primary point of contact** for the HRB during the review process and the management of the award, if successful.

#### Each member of the Leadership Team must be

An independent investigator who may be an academic or a health and care practitioner who

- Has a **PhD or MD degree**. If they do not have a higher degree but can demonstrate equivalent<sup>4</sup> research experience, please contact the HRB office to check eligibility before submitting;
- and
  - hold a post (permanent or a contract that covers the duration of the award) in an Institution of Higher Education on the island Ireland as an independent investigator. Please note that the Lead Applicant must hold a post at a university in the Republic of Ireland;
- or
- is a contract researcher with a contract that covers the period of the award, who is recognised by his/her institution as an independent investigator and will have an independent office at the institution for which he/she will be fully responsible for at least the duration of the award;
- or
- is an individual who will be recognised by his/her institution upon receipt of the HRB Collaborative Doctoral Award as a member of the academic staff or a contract researcher as defined above.

#### The leadership team must demonstrate

- Strong track record in patient-focused research demonstrated by their contribution to knowledge, research outputs<sup>5</sup> and expertise in accelerating the transfer and application of research evidence into real-world applications;
- Complementarity of disciplines, skills and expertise as relevant to the research and training programme, including from under-represented professions/disciplines relevant to the strategic leadership of the programme;
- Clear strategic vision of the research programme;
- Strong collaborative and networking expertise;
- Strong track record in training supervising and mentoring early and mid-career researchers.

\*<u>Research outputs</u>: There is no minimum number of research outputs required for eligibility of each individual; however, the individuals must be able to show appropriate research output. In line with the San Francisco declaration for research assessment DORA<sup>6</sup> and the implementation of its principles, research outputs may be peer-reviewed articles, research data and datasets, research material, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, non-peer-reviewed publications such as policy briefs, national reports, research reports, evidence synthesis, or others as relevant.

<sup>&</sup>lt;sup>4</sup> At least four years active research experience post-primary degree

**The leadership team** <u>jointly</u> will have to fulfil the eligibility requirements listed below. This means one member of the team can fulfil all criteria <u>OR</u> different members can fulfil one or two criteria as long as all three criteria are met. Each criterion <u>must be met in full</u> by at least one member of the leadership team. The eligibility criteria are as follows:

- 1. At least <u>seven years</u> of research experience beyond PhD or MD and prior to the CDA pre-application deadline (17 December 2020); this means the PhD or MD must have been successfully defended (not conferred) in 2013 or before;
- 2. A track record in leading research projects and programmes through securing as Principle Investigator or co-Principle Investigator at least <u>three</u> independently peer-reviewed, research grants <u>with at least one of a value equal to or above €200K</u> from a recognised national and/or international funding agency/council over the last 7 years. This would also include being a work package leader of a research grant from the European Commission with a value equal to or <u>above €200K</u>. For the purposes of this scheme fellowships or other personal awards are eligible but travel bursaries/awards are not considered as eligible research grants;
- 3. Track record in supervising and mentoring PhD candidates demonstrated by being the primary/principle supervisor, as recognised by the higher education authority, of a <u>minimum of three completed PhD</u> <u>recipients.</u>

### Individuals not eligible to apply as members of a Leadership Team in this round

Directors or Co-Directors of CDA Programmes awarded in 2018 and 2019 <u>will not be eligible</u> to apply as members of a leadership team in the 2021 round of the call.

### 7.2 Core Partners

A Core Partner is defined as an individual or organisation participating fully in the consortium with a leading role and significant responsibility, including designing and managing the training programme, supervising and mentoring PhD candidates and potentially receiving a portion of the programme budget. Ideally, Core Partnerships should include collaborations with health researchers, health and care practitioners and key stakeholders, knowledge users or other experts. The number of core partners will depend on the proposed research and training programme and the different individual research projects within the overall programme. However, it is envisaged that a <u>minimum of 5 partners</u> should be proposed in order to provide a breadth and depth of skills, knowledge and expertise within the consortium core team (Co-Directors and Core Partners). The <u>maximum</u> number of <u>core partners is 10</u>.

Core Partners can be based in Higher Education Institutions/research institutions, any type of healthcare setting, health agencies, local government, voluntary organisations or commercial settings as appropriate to the programme of training and research activities. They can be internationally based.

The core partners identified to act as primary supervisors/mentors of a PhD candidate project must demonstrate a strong track record in contribution to knowledge in the specific research area of the project as well as a track record in supervising and mentoring early-stage and preferably mid-stage researchers.

However, the core team may also wish to address capacity building in supervisory experience. For example, individuals with relevant expertise for the delivery of the programme but less experience supervising PhD candidates could be co-supervisors of selected projects. They should be mentored by more experienced researchers who would also act as the main supervisor/mentor of the PhD candidate.

Patients and other stakeholders (e.g. patient organisations, health agencies, policy makers, etc.) must be included as Core or Associated Partners depending on their role within the programme.

### 7.3 Associated Partners

An Associated Partner is defined as an individual or organisation which has a supportive role in the training and/or the research component of the Programme by providing discrete and specialist expertise. This may, for example, include access to specific equipment or groups, specialist staff time, trials advice or other support, access to data and/or patients, instruments or protocols. An Associated Partner may also act in an advisory capacity, provide training in a specific methodology, host PhD candidates for placements/collaborations, or provide a workshop/training module. Associated partners do not supervise PhD candidates. We would expect a maximum number of 10 associated partners in each programme, however more can be proposed when properly justified. Information on Associated Partners will be required at Full Application stage only.

Associated Partners can be based in Higher Education Institutions/research institutions, any type of healthcare setting, health agencies, local government, voluntary organisations or commercial settings as appropriate to the programme of training and research activities. Associated Partners can be internationally based.

Patients and other stakeholders (e.g. patient organisations, health agencies, policy makers, etc.) must be included as Core or Associated Partners depending on their role within the programme.

**Note:** Profile details <u>must</u> be provided for ALL Associated Partners. In addition, at <u>Full Application stage</u> each associated partner <u>must</u> complete a **Partner Agreement Form.** The HRB advises that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up collaboration agreements.

**Note:** If the success of an application is dependent on access to healthy volunteers or patients, vulnerable population groups, data, databases or a link to an existing national or international study (e.g. an existing cohort or longitudinal study) and/or if the study is part of an ongoing trial, it is advised that you include these details (including the full protocol in the case of an ongoing trial) and the relevant key gatekeepers as Associated Partner within your application. This will greatly assist the reviewers and panel members in reviewing aspects of commitment and access and overall project feasibility.

### 7.4 Public and Patient Involvement (PPI) in research

The HRB promotes the active involvement of members of the public in the research that we fund. This includes patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. PPI is research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. It is distinct from and additional to activities which raise awareness, share knowledge and create a dialogue with the public and it is also distinct from recruitment of patients/members of the public as participants in research.

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

Involving members of the public in research can improve quality and relevance. It can:

- Provide a different perspective even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition
- Make the language and content of information such as questionnaires and information leaflets clear and accessible

- Help to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants
- Help to ensure that the research uses outcomes that are important to the public
- Identify a wider set of research topics than if health or social care professionals had worked alone
- Help to increase participation in your research by making it more acceptable to potential participants

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

In the application, you are asked to describe any public involvement in your research throughout the various stages of research design, conduct, analysis and dissemination. We recognise that the nature and extent of active public involvement is likely to vary depending on the context of each study.

We strongly advise that you consult with your Host Institution who may be able to provide guidance and support on PPI in research.

# 8. FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB supports **open research**<sup>7</sup> and open publishing directly through the **HRB open research platform**<sup>8</sup>. The HRB is now driving the making of research data **FAIR** (Findable, Accessible, Interoperable and Re-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

**FAIR data principles**<sup>9</sup> provide guidelines for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals. For researchers, the move to FAIR and open data, where applicable, means researchers should consider data management issues and find suitable data repositories at the research planning stage. Applicants will have to provide information about their plans for data management and data sharing at application stage.

In line with the HRB's policy on management and sharing of research data<sup>10</sup>, all successful applicants are required to submit a completed data management plan (DMP) to the HRB at the beginning of the award and a final updated version of the DMP with the final report at the end of the award.

# For this funding call, the initial data management plan for each PhD project is required <u>four months after</u> <u>the start date</u> of the programme.

- The DMP will need to be submitted alongside a declaration of completion from the designated representative(s) within the Host Institution.
- Applicants will have to provide an outline of their plans for data management and data sharing in the full application inclusive of the costs associated to the plan.
- The timing for completion and submission of the DMPs must be also included among the objectives and deliverables of the programme.

<sup>&</sup>lt;sup>7</sup> http://www.hrb.ie/funding/policies-and-principles/open-research/

<sup>&</sup>lt;sup>8</sup> https://hrbopenresearch.org/

<sup>&</sup>lt;sup>9</sup> https://www.nature.com/articles/sdata201618

<sup>&</sup>lt;sup>10</sup> https://www.hrb.ie/fileadmin/user upload/HRB Policy on sharing of research data.pdf

# 9. 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. It is normally the employer of the Lead Applicant, but it may be another institution designated by the Lead Applicant and Core Partners, where it is clearly justified. The Host Institution is the body in charge of the financial and administrative co-ordination of the award. A list of approved HRB Host Institutions can be found at <a href="https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institution">https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institutions</a>. In order to be eligible to apply for funding, an Institution must be an <a href="https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institution">https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institutions/</a>. In order to be eligible to apply for funding, an Institution must be an <a href="https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institution">https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institutions/</a>. In order to be eligible to apply for funding, an Institution must be an <a href="https://www.hrb.ei/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institution">https://www.hrb.ei/funding/funding-schemes/before-you-apply/all-grant-policies/approval-of-host-institutions/</a>. In order to be eligible to apply for funding, an Institution must be an <a href="https://www.hrb.ei/funding-schemes/before-you-apply-schemes/before-you-apply-schemes/before-you-apply-schemes/before-you-apply-schemes

It is expected that each PhD candidate will register for their PhD studies at the host institution or any other partner institution in the Republic of Ireland. In case of international placements for an extended period of time, a clear justification including the arrangement for the cohort-based approach and peer-learning must be provided.

Note: At <u>Pre-Application stage</u>, Institution Letters of Support must be provided for the Lead and co-Lead Applicants in a contract position. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [Institution – insert name] which is the 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 CDA 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-doctoral researchers. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

# **10.** Training Programme

The training programme should have sufficient academic breadth to give PhD candidates flexibility during their research education as well as exposure to international and inter-sectoral mobility.

In line with several documents describing the principles<sup>11</sup> for innovative and advanced doctoral training and with the HRB experience in funding and supporting PhD structured programmes, each consortium <u>must</u> provide a <u>structured training programme</u>. This structured training programme <u>must provide</u> an appropriate balance between the training elements and sound research projects for each trainee that will benefit patient care and health. The Programme should generally include the following elements:

Access to training specialist and generic skills modules/courses, including digital ones, by linking with the current training infrastructure available in the institution(s) involved in the consortium and/or

<sup>&</sup>lt;sup>11</sup> Principles of innovative doctoral training

http://ec.europa.eu/euraxess/pdf/research\_policies/Principles\_for\_Innovative\_Doctoral\_Training.pdf; IUA PhD Graduate Skills Statement http://www.iua.ie/wp-content/uploads/2014/10/IUA-PhD-Graduate-Skills-Statement-20141.pdf; National Framework for Doctoral Educationwww.hea.ie/sites/default/files/national\_framework\_for\_doctoral\_education\_0.pdf

through already established national doctoral programmes (e.g. <u>ICAT</u>, <u>SPHeRE</u>) while at the same time maintaining the identity of the CDA programme and CDA cohort.

- Elements of placements/secondments which might include inter-sectoral and/or international elements (including virtual) aimed at experiential learning, networking and collaborating. For long period of time for international or inter-sectoral placements/collaborations a justification must be provided to clarify the arrangements for the trainee in terms of the cohort-based approach and the structured training.
- Opportunities to develop different research and analytical methodologies<sup>12</sup> and skills (e.g. qualitative or quantitative skills, clinical trials, epidemiology, ethics, public and patient involvement, implementation science, study design, data management/stewardship and open research data, and data collection, statistical analysis, secondary data analysis and data linkage, protection of human subjects etc.);
- Some level of contribution by each trainee to finalise his/her PhD research question and methodology with the relevant supervisory team before officially starting the project.
- Mentorship environment with joint supervision and mentoring from investigators from different disciplines, methodologies, professions and/or sectors, as appropriate;
- Opportunities to develop professional and transferable competencies (teamwork, communication, creative thinking, negotiation skills, innovation and leadership, entrepreneurship, management, ethics and research integrity, intellectual properties and commercialisation, regulatory science, etc.).

Given the nature of this training programme and the potential diversity of educational backgrounds and research interests in a cohort, it is expected that the individual training will vary and that a training plan will be customised with the supervisory team for every trainee through a personalised Career Development Plan; in addition to research objectives, this plan should comprise other more generic training and career needs, including planning for publications, participation at conferences and other dissemination activities, etc.

In addition to the PhD qualification each programme is strongly encouraged to confer, on each PhD candidate, a diploma supplement (e.g. transcript) that acts as a record of all training carried out as part of the doctoral programme. This is referenced in the *Framework for Qualifications of the European Higher Education Area* from the Bologna Working Group, Third Cycle<sup>13</sup> (Doctoral Degree/PhD). This additional record aims to enhance recognition of the training received during the doctoral training within Europe and may enhance the future employability of these PhD candidates.

At the end of the four years, PhD candidates should be able to demonstrate:

- Their engagement in an original piece of research for their doctorate that has the ultimate goal of benefitting patients
- Research outputs with high applicability to patient care and health
- Broad knowledge of the themed research area
- Advanced knowledge in the area of their individual PhD project
- Knowledge and understanding of the relevant research methodologies and techniques (including problem analysis and resolution skills, scientific reasoning and logic)
- Knowledge and understanding of the broader research environment (including research ethics & integrity, science and society, commercialisation)
- Project and time management skills

<sup>&</sup>lt;sup>12</sup> Please note that some of the modules offered though the SPHeRE Diploma (to be launched soon) could be useful in this regard <sup>13</sup> <u>http://ecahe.eu/w/index.php/Framework\_for\_Qualifications\_of\_the\_European\_Higher\_Education\_Area</u>

- Communication skills, both written and oral
- Team working

<u>Please Note:</u> A provisional but **mandatory Training Programme Summary Chart** will be requested as part of the training overview component of the pre-application form. This chart should be a clear visual interpretation of the overall training programme. It is expected that this chart would be updated/revised at full application stage if required. There is also an option to upload a non-mandatory training programme support file with the pre-application form which can be updated/revised at full application stage. Each of these files can be a maximum size of 2 MB per document and can be in the format .doc .docx or .pdf.

# 11. Programme Management and Governance

It is expected that each awarded consortium will put appropriate management and governance structures in place (e.g. Executive Team, Steering Committee, Programme Management Committee, Scientific Advisory Board, etc.) to ensure the efficient operation of the collaborative team and the delivery of the main objectives of the training programme.

The main objectives of these structures should be:

- To oversee the delivery and strategic development of the whole programme;
- To oversee the open and transparent selection of the PhD candidates;
- To monitor any ethical, Intellectual properties, data protection, trial monitoring issues and other relevant elements;
- To monitor the coordination of the training programme;
- To monitor the day to day management and financial monitoring of the programme.

There is flexibility for the Programme Director, Co-Director and the core team to propose appropriate management, governance and oversight structures as relevant to the proposed programme. Each consortium may also put in place additional arrangements where relevant e.g. Trial Steering Committees, Data Monitoring Committees etc. These requirements will be defined in detail at the time of the award contract.

# 12. Access and support from clinical research infrastructure

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

# **13.** The General Data Protection Regulation (GDPR)

The **General Data Protection Regulation** (GDPR) came into force on 25 May 2018. As a result the <u>applicant</u> <u>team</u> will be asked through GEMS to **confirm you understand** that personal data provided as part of this application, including but not limited to CV information, may be shared with person(s) based outside of the European Economic Area (EEA) for the specific purpose of obtaining peer reviews of this application. International reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Individual peer reviewers are selected for their specific expertise in relation to submitted applications, and can be based anywhere in the world.

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

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

# 14. Application, Review Process and Assessment Criteria

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

The Collaborative Doctoral Awards scheme will use a two-stage application process consisting of:

- 1. Open call for Pre-application stage
- 2. Invitation of selected applicants to submit a Full Application.
- <u>GEMS will close the pre-application stage</u> automatically on the **17 December 2020, at 13:00**.

Prior to final submission to the HRB, all applications must first be reviewed and approved within GEMS by the Dean of Research (or equivalent) at the Host Institution. It is critical therefore that the Lead Applicant leaves sufficient time in the process for the signatories in their nominated Host Institution to review, seek clarifications and approve applications prior to the final submission date. This may involve being aware of and complying with any internal Host Institution deadlines for review and approval, distinct from the HRB deadline.

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

The HRB is a signatory of the San Francisco Declaration of Research Assessment **DORA**<sup>14</sup> and has revised the lead applicant's and the research team sections in all the funding schemes supporting research careers and we now ask questions, such as personal declaration, most important contributions to scientific knowledge

<sup>&</sup>lt;sup>14</sup> https://sfdora.org/

Collaborative Doctoral Awards in Patient-focused Research 2021

and/or additional expertise matching the role in the application with relevant research outputs, and synergistic activities. They aim to provide additional information on the value, quality and impact of the applicant's work and the suitability of the applicant to the funding scheme and the research project proposed.

Although the HRB has never guided reviewers to consider impact factors or H-index, we now explicitly guide all reviewers to assess the track record of the lead applicants and research team based on

- The content, quality and impact/influence of the research outputs in the research field and/or in policy and practice.
- Different types of research outputs in addition to peer-reviewed articles (e.g. research data and databases, research material, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence to health policy and practice, outreach and/or knowledge exchange activities, media coverage or other relevant activities).
- Active research experience of the Lead Applicant, so career breaks should be also taken into consideration and appropriate adjustments made when considering the record and impact of outputs.

### Pre-Application Stage

The Pre-application form will focus on (1) the full details of **the leadership team and core partners**,(2) the case for **the research thematic area** and (3) **the case for a proposed doctoral programme**.

The pre-applications submitted will be checked for eligibility, and will be sent to a specially convened international review panel for analysis and comments. Members of the review panel will be selected based on the range of disciplines, methodologies and expertise appropriate to the scheme.

The Pre-application Review Panel will meet virtually to discuss the eligible pre-applications and will rank them based on the three assessment criteria below, which have <u>equal weight</u>.

- 1. **The consortium**: Appropriate track record, as relevant to this scheme and application, and breadth of expertise and skillset of the leadership team and the core partners;
- 2. **The research programme**: The case for the research programme to address an important health challenge and to advance and translate patient-focused research findings, with impact, to health and patient care is well made;
- 3. **The doctoral training programme:** the case for, and justification of, the proposed doctoral programme in the research area and the coherence and quality of the outlined training framework.

Feedback will be provided to all applicants upon completion of the Pre-application review process.

### Full Application Stage - by invitation only

A selected number of Lead Applicants and their teams will be invited to full application stage. Full applications must be submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie) and information from the Pre-application stage will automatically feed into the invited Full Application forms.

Please note that the panel will have made their selection based on the information provided at Pre-application stage. The Lead Applicant will have the opportunity to make small revisions from Pre-application to Full Application stage (e.g. addition of expertise/partner, revision of targeted profession/disciplines for training, strengthening the stakeholder participation, etc.), particularly if addressing the panel feedback provided after the Pre-application stage. However, Full Applications should reflect a development of the relevant Pre-applications rather than a radically different approach.

Full applications, once submitted, will undergo a <u>two-stage</u> assessment process as follows:

#### Stage 1 – International Peer Review, Public Review and Applicant Response

For each full application the HRB aims to receive written feedback from at least three international peer reviewers and two public reviewers.

<u>International peer reviewers</u> 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. Peer reviewers will focus on the stated assessment criteria for the call and will provide comments as well as a score which is visible to the HRB and to panel members. The individual scores received from the international peer reviewers for each application will be averaged by the HRB and a preliminary short list compiled. A higher number of Lead Applicants will be selected in this step than can be interviewed for further review by an international shortlisting panel.

For the purposes of this scheme, the peer-reviewers will be asked to comment and score mainly on the following criterion:

### • The Research Programme

- a. The likelihood and potential of the programme to advance and translate patient-focused research findings, with impact, to health and patient care;
- b. The quality and coherence of the research projects within the overarching thematic area (including research design and methodologies, feasibility and appropriateness to doctoral training);

We also ask reviewers to provide feedback, but no score, on the

### • The Consortium

- a. The leadership team;
- b. The consortium: breadth of expertise, skillset, appropriate PPI and other stakeholders' participation;

<u>Public reviewers</u> will only assess the quality of PPI in the proposal and will provide comments and an overall rating which will be shared with the panel. Public reviewers will not provide a score.

Public Reviewers are asked to comment on the following:

- 1. The Plain English Summary (Lay Summary)
- 2. Relevance of the Proposed Research Question
- 3. Public and Patient Involvement in development of and throughout the project
- 4. Research Design inclusion of research participants (where applicable)
- 5. Dissemination and Potential Impact of the Proposed Work

Both peer and public review comments will not include any reference to the reviewer's identity or their submitted scores or rating.

### Applicant response

The Leadership Team will be provided with a time-limited opportunity to respond to peer and public review comments (see Section 16: Timeframe).

Once notified that the application is short-listed the peer-review and public review comments will be made available to the Leadership Team on their GEMS personal page. Each Leadership Team will have <u>10 working</u> <u>days only</u> to submit their response through GEMS, and the response has a maximum word count of **2500** words, including references. This wordcount is broken down into <u>2000 words only</u> for the peer review response and <u>500 words only</u> for the public review response. The response will be provided to members of the Interview Panel, in advance of the interview Panel meeting, along with the application, the peer and public review comments and the review discussion summary provided to lead applicants at the conclusion of the Preapplication stage.

This phase of the assessment process is extremely important, and the response will likely play a critical role in whether a proposal ultimately 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 weaknesses or concerns. It also provides the Leadership 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 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 a minimum, acknowledge it. Responses that could be construed as argumentative should be avoided. Please note HRB reviewers volunteer their own time in reviewing grant applications.

### Stage 2 – Interview Panel

The Interview Panel membership will overlap with that of the Pre-application Panel. Panel members are selected based on the range of applications received and the expertise and skillset required (e.g. research area and methodological and analytical approaches, coaching and mentoring, knowledge translation/applied health research, etc.). The Interview Panel will meet in Dublin or virtually. The Leadership Teams invited to submit Full Applications will each be invited to attend an interview.

The reviewers will assess all full applications based on the following <u>three assessment criteria</u>, which have <u>equal</u> <u>weight</u>. Successful programmes must score highly in all criteria.

### 1. The Consortium

- a. The leadership team;
- b. The consortium: breadth of expertise, skillset, appropriate PPI and other stakeholders' participation;

#### 2. The Research Programme

- a. The likelihood and potential of the programme to advance and translate patient-focused research findings, with impact, to health and patient care;
- b. The quality and coherence of each doctoral research project within the overarching thematic area (including research design and methodologies, feasibility and appropriateness to doctoral training);

#### 3. The Programme Training and Governance

a. The quality and coherence of the training framework;

b. The programme's management, oversight and governance.

The review on the PPI component does not constitute a standalone scoring criterion in this round, however it will be taken into account by the Panel and may influence discussions under each assessment criterion as relevant to the research programme.

The recommendations of the Interview Panel will be presented for approval at the next scheduled HRB Board meeting. When the Board of the HRB has approved the process and recommendations, HRB staff will contact the applicants to notify them of the outcome. It is estimated that the review process, from the deadline of the call to the final HRB board decision, will take approximately nine months.

<u>Note</u>: The balance between the **research thematic areas** will be the **first ranking factor** to prioritise proposals with the same scores in the shortlisting and Interview Panel ranking list. **In line with** the **HRB Gender Policy**, which came into effect on 1 June 2016<sup>15</sup>, the **gender balance within the core team** (leadership team and core partners) will be the **second ranking factor**.

The HRB will aim to provide specific feedback on the review process to all applicants.

# **15. Conflict of Interest**

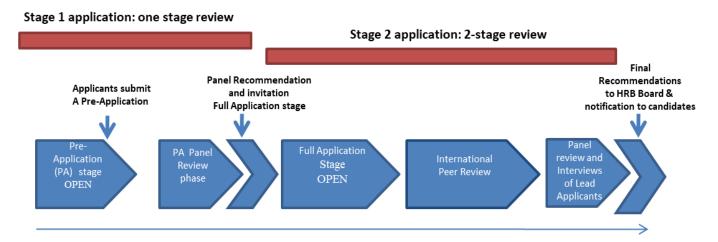
Conflict of interest rules *are applied rigorously.* Where a conflict of interest exists, the reviewer is requested to inform the HRB immediately so that an alternative reviewer may be appointed. International peer reviewers will not provide comments or scores on any application on which they have a conflict of interest.

Reviewers must adhere to high standards of integrity during the peer review process. They must respect the intellectual property of applicants and may not appropriate and use as their own, or disclose to any third party, ideas, concepts or data contained in the applications they review.

<sup>&</sup>lt;sup>15</sup><u>https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-gender-in-research-funding/</u>

# 16. Timeframe for 2021 call

The deadline for submission of Pre-Applications through GEMS is **17 December 2020 by 1pm**.



~ 12 month timeline

Pre-Application Stage	
28 September 2020	Call opening for Pre-Application stage
17 December 2020	Deadline for Pre-application submissions
Mid-January 2020	Eligibility completed and start of shortlisting review
	by Panel
Mid-February 2021	Shortlisting Panel meeting
Late February 2021	Notification to all applicants and invitation to full
	application stage for a selected number of applicants

Full Application Stage	
Mid-May 2021	Submission of full applications
Mid-August 2021	End of peer and public review
Early-September 2021	End of the Applicant Response Phase
1 <sup>st</sup> - 2 <sup>nd</sup> week October 2021	Interview Panel Meeting
Early November 2021	Board Approval
November 2021- February 2022	Budget negotiation and contracts
March-April 2022 onwards	Start of the awards and recruitment of PhD
	candidates
September 2022	Cohort of PhD candidates start

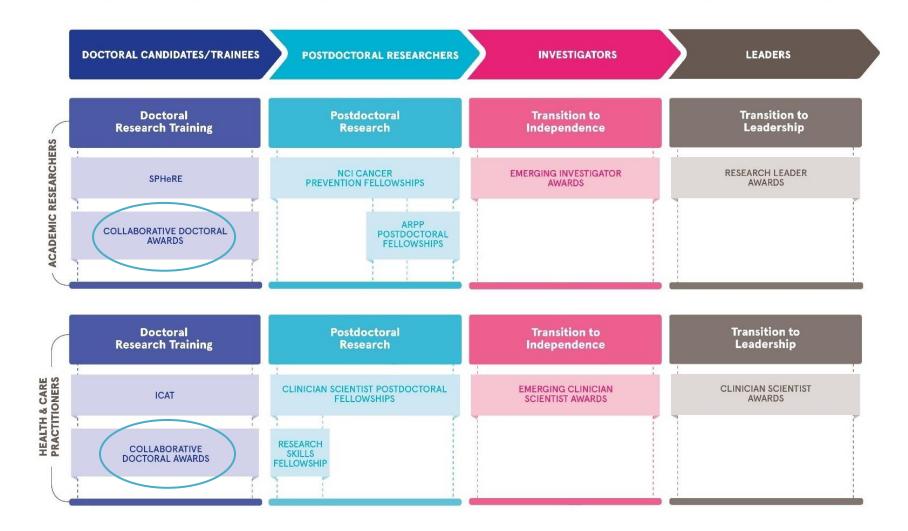
# 17. Contact for pre-application stage

For further information on the Collaborative Doctoral Awards in Patient-focused Research 2021 please contact:

Dr Anne Costello Project Officer Pre-Award Team Research Strategy and Funding t 353 1 2345 157 e acostello@hrb.ie

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 <u>https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/appealing-funding-decisions/</u>.





# Appendix II - Detailed Guidance for the CDA 2021 Pre-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: <u>https://grants.hrb.ie</u>

### Please refer to the GEMS Technical Guidance Note for further information.

The lead applicant must create the application, but it can then be jointly completed with named co-lead applicants and core partners.

- Lead applicants can register on GEMS and they will receive an email to confirm their registration and log in details. The lead applicant can then add information on their basic CV details in the 'Manage my details' section of GEMS.
- Lead applicants previously registered on GEMS can login to GEMS and update any information regarding their CV details in 'Manage my details'.

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

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

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

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### **Host Institution**

A *HRB Host Institution* is a research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all of the HRB's award schemes. The **Host Institution for the award** is normally that of the Lead Applicant but it may be another organisation/institution designated by the research team, where it is clearly justified. Information on the current approved Host Institutions and on the application process for research performing organisations to be approved as HRB Host Institutions is available on the HRB website<sup>16</sup>.

<u>Please note</u> the application process for Host Institution approval is separate to the CDA application process and a Host Institution must already be <u>approved</u> no later than two calendar months prior to the closing date of a given call in order to be eligible to apply to that call.

In GEMS you will be asked to identify a Host Institution (from this list) and type it in full (do not use acronyms such as UCD, TCD, NUIG). Once you have entered the first 3-4 characters of the Host Institution, you will be assisted with auto-select options. It is important that the HI name is entered accurately and in full as an incorrect entry may result in delays in attaining Host Institution approvals.

### **Signatory Notification (within Host Institution)**

Once the Host Institution is selected, at the initial stages of application creation, the Lead Applicant can notify the <u>authorised signatory</u> (Dean of Research or equivalent person authorised to endorse research grant applications for the Host Institution) in that Host Institution, of the lead applicant's intention to submit an application to the CDA 2021. The signatory's details are pre-populated in the system so the applicant just needs to click 'Notify Dean of Research' within GEMS. We recommend that you **notify the Host Institution 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 and, if they have any queries or clarifications, they can engage directly with the Lead Applicant to resolve them. The Host Institution signatory must confirm their willingness to participate as Host Institution 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.

# **1. Doctoral Programme Summary**

### **1.1 Programme Title**

This should be descriptive and concise and should reflect the aim of the overall programme. Please note a <u>200</u> - <u>character limit</u>.

### **1.2 Doctoral Programme Lay Summary**

Please describe what you propose to do; say why you think it is important to complete this work and how it will be done. A lay summary needs to be written as a **plain English summary** such that it is clear, easy to understand,

<sup>&</sup>lt;sup>16</sup> http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/

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and is easily accessible to a lay audience. The lay summary may be used when providing information to the public with regard to the variety of research funded by the HRB and may be published on the HRB website. Please note that the Lay Summary can be updated at full application stage, however, it is expected that the overall theme will not change. The word limit is <u>300 words</u>.

#### **1.3 Keywords**

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

### 2. The Consortium

The application will support a newly formed or an existing consortium of collaborative, cross-disciplinary and cross-sectoral partners, including from overseas and industry, where relevant. The Consortium should consist of academics and health and social care professionals from any healthcare setting (primary, secondary, tertiary and community) and other experts as relevant to the training and research objectives of the programme. It is envisaged that each consortium will have strong stakeholder participation (e.g. patients, charities, policy makers, decision makers, etc.). The concept is that such consortia should create a whole that is greater than the sum of separate activities.

The consortium must:

- Contain the necessary breadth and depth of research and/or professional expertise;
- Have the appropriate cross-disciplinary and/or cross-border and/or inter-sectoral approaches by breaking down the discipline, professional and sectorial barriers in research, and preferably including international collaborations;
- Have strong public and patient, or other relevant stakeholder, involvement.

You should also highlight how the leadership team (Lead and Co-Lead Applicants) will address the mentoring and coaching of less experienced core partners in the consortium, if applicable, during the award in order to enhance their skillset in research, training and mentoring, collaboration, award management and future leadership.

### 2.1 Collaborative and Team-based approach

- Please state if this is an existing or newly formed consortium.
- Describe the choice of partners, the overall complementarity of skills, expertise and disciplines within the team, and how they will converge and work together to deliver and support the programme.
- If this is an existing consortium, please provide details of the track record and achievements of the consortium to date.

The word limit is 400 words

### 2.2 Summary table - Core Consortium

For each member of the consortium please add

- name and current position
- institution (affiliation)

• role on the Programme (Leadership team member or core partner) and the specific contribution to the Doctoral Programme as well as the amount of time each member will contribute to the award as a percentage or proportion of a full time equivalent (FTE). **The word limit is 50 words.** 

# 3. Leadership team - Lead and Co-Lead Applicants

### 3.1 Leadership team number

Please select 2 or 3

### **3.2 Lead Applicant details**

### **GEMS Profile Details - Basic CV information**

The Lead and co-Lead Applicant are required to fill in CV details in the 'Manage my Details' section of GEMS, which can be found on the left hand side menu once you log in (if previously registered on GEMS this information will be pre-populated on the Lead Applicant's Details page, however, applicants should ensure this information is up to date and correct.

The **basic CV details** (name, institution, profession, education and employment history) will be <u>automatically</u> included in this application.

The **funding record** (including HRB grants) most relevant to this application and **research outputs** will be requested manually so you <u>do not need</u> to enter them in GEMS under "manage my details".

### Gender

This question is included with the application form in light of the **HRB Gender Policy.** The HRB has the responsibility to support both women and men to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. The information will not be shared with reviewers and it is for HRB internal use only.

Please select

- Man
- Woman
- Other gender identity
- Prefer to not disclose

### 3.2.1 ORCID iD

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

### **3.2.2 Eligible Position**

Does the Lead applicant hold a <u>permanent post</u> in a HRB approved Host institution (HI) in the <u>Republic of Ireland</u> and do Co-Lead Applicant(s) hold a <u>permanent post</u> in an Institution of higher education on the <u>island of Ireland</u>? Y/N Where a Lead or Co-lead applicant holds a contract position rather than a permanent position, **an Institution Letter of Support** must be provided. This formal letter, on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [*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 recognised by the host institution upon receipt of the HRB CDA 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-doctoral researchers. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

### 3.2.3 Type of Researcher

### Please select:

- Academic
- Health and Care Practitioner (with a joint academic appointment)

### 3.2.4 Career breaks

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

### 3.2.5 Contribution to knowledge

### 3.2.5.1 Most relevant funding track record

Please reference <u>up to five</u> independently peer-reviewed research funding awards (including those received from the HRB) most relevant to this application and please specify your role on each: Principle Investigator, Co-Principle Investigator (Co-Lead), Co-Applicant or Collaborator.

### 3.2.5.2 Most relevant research outputs

- Please reference <u>up to ten research outputs that are most relevant to your role on this application</u>. Please include one reference per output, if applicable, and explain very briefly for each (e.g. three-four lines) your specific contribution and the significance and impact to the field or to policy and/or practice.
- Please provide the total number of peer reviewed publications which you have authored and/or coauthored.
- Please add the weblink to your full list of peer-reviewed publications.

### The limit is 600 words.

**Please note** in line with the San Francisco declaration on Research Assessment **DORA**<sup>17</sup> the HRB ask reviewers to consider the value, quality and impact of the applicant's work. Applicants may reference research outputs such as peer-reviewed publications, research data and databases, research material, audio/video products, national and/or international reports or briefs, models and protocols, software, evidence of influencing policy

<sup>&</sup>lt;sup>17</sup> <u>https://www.hrb.ie/funding/funding-schemes/before-you-apply/how-we-assess-applications/declaration-on-research-assessment/</u>

and/or practice, outreach and/or knowledge exchange activities, media coverage or other research-related relevant activities.

**Note:** Please do not include information related to H-indexes, impact factors, or any type of metric that refers to the journal, publisher, or publication platform, rather than to the individual output item; the scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published.

### 3.2.5.3 Contribution to training and development of other researchers

Describe **your experience as supervisor and/or career/personal mentor** to researchers at different career stages (PhD and MSc candidates, postdoctoral/research fellows) as well as other individuals (e.g. clinical fellows, research assistants) including those from outside your own discipline, if any. Briefly describe the names of these individuals, their position while in your team, their position now and your actual contribution to their career development and progression. The word limit is **200 words** 

### 3.2.5.4 Contribution to wider research community and society

#### Academic profile and synergistic activities

The aim of this section is to enable a rounded recognition of your career to date by providing a holistic overview of your academic and professional profile.

Provide some examples (bullet points) under selected headings as most relevant to your career and experience to date and not addressed in other section of your CV. The assumption is that not all Lead Applicants will, necessarily, have experience under all these headings. These activities will be assessed in the overall context of the career stage of the individual, the role in the programme and the objectives of this scheme.

Examples of topics you may address are listed below. This list is meant as guidance and you do not need to address all these topics and may choose to include others. The word limit is **200 words.** 

- Stakeholder engagement and/or PPI activities/initiatives;
- Collaborative & cross disciplinary research;
- Research integrity;
- Contribution to Open Science (open data, data sharing and open access, workshops/seminars);
- Knowledge translation activities that best relate to the work described in your application. E.g. communication & dissemination (beyond publications), development of IP (patents, licenses), development of guidelines and standards, knowledge exchange and outreach activities;
- Teaching and other related activities (e.g. coordinator of modules, courses, etc);
- Peer-review and/or panel review contributions;
- Networking activities;
- Memberships to committees, scientific boards, editorial boards, national or international groups etc;
- Honours/awards, national and international profiling, plenary lectures;
- Administrative and managerial tasks, project management and other professional development.

### **3.2.5.5 Personal Declaration**

Briefly describe why you are well-suited to your role of member of the Leadership Team on this application.

You may refer to your **leadership expertise**; **expertise** in relation to **patient-focused research**, particularly your role in **accelerating the transfer and application** of research findings and evidence into effective applications in a real-world healthcare/clinical setting; training and career development of early career researchers; professional skills such as negotiating and influencing, networking and collaborative work, cross-disciplinary and/or inter-sectoral work; or other relevant expertise. The word limit is **250 words**.

#### Leadership Team eligibility: (For Pre-application form only and hidden in review PDF)

Please indicate in the relevant box which team member(s) fulfil each listed eligibility criterion:

- At least <u>seven years</u> of research experience beyond PhD or MD and prior to the CDA pre-application deadline (17 December 2020); this means the PhD or MD must have been successfully defended (not conferred) in 2013 or before;
  - Insert name of team member(s)
- A track record in leading research projects and programmes through securing, as Principle Investigator or co-Principle Investigator, at least <u>three</u> independently peer-reviewed research grants <u>with at least</u> <u>one of a value equal to or above €200K</u>, from a recognised national and/or international funding agency/council, over the last 7 years. This would also include being a work package leader of a research grant from the European Commission with a value equal to or <u>above €200K</u>. For the purposes of this scheme fellowships or other personal awards are eligible however travel bursaries/awards are not considered as eligible research grants.
  - Insert name of the leadership team member(s) and details of the research grants, if additional to those listed in section 2
- Track record in supervising and mentoring PhD candidates, demonstrated by being the primary/principle supervisor as recognised by the higher education authority, of a <u>minimum of three completed PhD</u> recipients.
  - Insert name of the leadership team member(s) and please ensure the relevant detail is listed in section 2.

### 4. Core Partners

Although there is no specific limit in the application form, it is envisaged that a <u>minimum of five partners and</u> <u>maximum of 10</u>, including those from overseas where relevant, should be included in order to provide an appropriate breadth and depth of skills, knowledge and expertise within the <u>consortium core team</u> (Co-Leads and Core Partners).

The Lead Applicant (LA) can add each Core Partner by entering their name on GEMS. If the Core Partner is already registered on GEMS, the system will find them and will allow the LA to select them. Alternatively, a partner can be added manually by entering their name and email details. GEMS will send them an email with login details to complete the registration process and will inform them that they have been invited by the LA to participate on the application as a Core Partner.

**Registered Core Partners** can decide whether to accept or reject their participation and **must consent to the application being submitted jointly in their name**. The approvals given by Core Partners for the stage 1 pre application will still be valid at full application stage. If a core partner rejects participation on an application the LA is informed and may revise the application accordingly. Core Partners who accept participation on an application will be able to complete their relevant sections of the application. All Core Partner information included at pre-application stage will be automatically populated in the full application form. Additional Core Partners may be added to an application by the Lead Applicant, at full application stage, if required (a proper justification will be required). When a Core Partner is added, GEMS will automatically email them to invite their participation, which they must approve. *The system will flag if another user is working on the application form at the same time via a pop-up warning. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data but it advisable that they contact the other person directly to avoid losing data when applying the override function.* 

Each Core Partner can manage their own **CV details** (name, institution, profession, education and employment history) under the 'Manage my Details' section of GEMS and this information will then be automatically included in this application.

Please <u>note</u> that the **funding record** (including HRB grants) and relevant **research outputs** will be requested manually and will not feed in from your GEMS profile.

### 4.1 How many Core Partners will work on this programme within the consortium core team?

### 4.2 Core Partner Details - to be included for each Core Partner

**Gender** This question is included with the application form in light of the **HRB Gender Policy.** The HRB has the responsibility to support both women and men to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. The information will not be shared with reviewers and it is for HRB internal use only. Please select:

- o Man
- o Woman
- $\circ \quad \text{Other gender identity} \\$
- o Prefer to not disclose

#### Participant Type

Please describe yourself as:

- o Researcher Academic
- Researcher Health and Care practitioner
- Health and Care Practitioner In practice only
- PPI Contributor
- o Knowledge User
- o Stakeholder from private sector
- o Other stakeholder or expert, please specify

#### **Career breaks**

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

### Funding track record – to be included for each Core Partner

Please reference <u>up to five</u> independently peer-reviewed research funding awards (including those received from the HRB) most relevant to this application. Please include the following information for each funding

award: Start Date; Duration; Currency; Total Award Amount in Euro (€); Name of funding body; Funding Body reference No; Grant Type; Title of award and Role on the award (Lead, Co-lead, Co-Applicant or Collaborator).' The word limit is **160 words**.

#### **Research Outputs:**

- Please reference <u>up to five research outputs that are most relevant to your role in this application.</u> Include <u>one reference</u> per output, if applicable, and explain very briefly (e.g. three-four lines) your specific contribution, the significance and impact to the field or to policy and/or practice for each entry.
- Please provide the total number of peer reviewed publications which you have authored and/or coauthored.
- Please add the weblink to your full list of peer-reviewed publications.

The word limit is **200 words.** 

**Please note** that in line with the San Francisco Declaration of Research Assessment **DORA**<sup>18</sup> the HRB ask reviewers to consider the value, quality and impact of the applicant's work. Core applicants may list research outputs such as peer-reviewed publications, research data and databases, research material, audio/video products, national and/or international reports or briefs, models and protocols, software, evidence of influencing policy and/or practice, outreach and/or knowledge exchange activities, media coverage or other research-related relevant activities.

**Note:** Please do not include information related to H-indexes, impact factors, or any type of metric that refers to the journal, publisher, or publication platform, rather than to the individual output item; the scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published.

#### **Personal Declaration**

Please briefly describe why you are well-suited to the role of Core Partner on this Collaborative Doctoral Programme. You may refer to your relevant research and analytical expertise and skills as well as your professional skills, such as negotiating and influencing, leadership, networking and collaborative work, cross-disciplinary and/or inter-sectoral work and/or other relevant expertise. The word limit is **250 words.** 

### Contribution to training and development of other researchers

If proposing to supervise or mentor one or more candidates, please further describe **your experience as supervisor and/or career/personal mentor** to researchers at different career stages (PhD and MSc candidates, postdoctoral/research fellows) as well as other individuals (e.g. clinical fellows, research assistants) including those from outside your own discipline, if any. Briefly describe the names of these individuals, their position while in your team, their position now and your actual contribution to their career development and progression. The word limit is **200 words** 

<sup>&</sup>lt;sup>18</sup> <u>https://www.hrb.ie/funding/funding-schemes/before-you-apply/how-we-assess-applications/declaration-on-research-assessment/</u>

# **5. Research Programme Description**

5.1 Overarching Aim of the Research Programme	35
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5.3 Total number of doctoral projects	35
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Provisional Project Title	35
Provisional Project Abstract	35
Primary research question of the Project	35
Targeted type of trainee and Supervisory Team	36
5.5 References - Research Programme	36

### 5.1 Overarching Aim of the Research Programme

Please state the overarching aim of the research programme. Please note this is at the level of the <u>research</u> <u>programme</u> and not the overall doctoral programme (inclusive of training and management elements). Please note a similar question will be asked at the level of the individual doctoral projects). The word limit is <u>100 words</u>

### 5.2 The Relevance and Importance of the Research Thematic Area

Please set out a case for the **relevance and importance** of this research project at this time in Ireland.

- Outline the problem to be addressed and the strategic importance for Ireland in terms of policy and practice (nationally and/or internationally); please reference the national strategy of relevance and any other relevant document/publication;
- Describe any systematic review, or alternative evidence collected systematically, supporting why this research project should be conducted now and include the knowledge gaps in the research area;
- Include a description of any pilot work/data already undertaken or the use of existing national or international data;

The word limit is **1500 words**.

### 5.3 Total number of doctoral projects

Please choose 4 or 5.

### **5.4 Doctoral Project Details**

For each proposed doctoral project, please provide the following details:

### **Provisional Project Title**

The limit is 120 characters

### **Provisional Project Abstract**

Please provide a brief overview of the proposed doctoral project. The word limit is **300 words**.

### **Primary Research Question**

Please provide the main research question of the project. The word limit is 50 words

### Targeted type of PhD candidate and Supervisory Team

- Please provide information on the type of candidate you are planning to recruit to conduct the project. Include why this type of candidate is required and describe the main skill sets and expertise which will be developed during the award.
- Please list the names of the individuals involved in the supervisory team, specifying who will act as primary supervisor, secondary, etc or mentor for the doctoral candidate undertaking this research project. Please also include for each their affiliated institution and their role on the project.

The word limit is **200 words**.

### 5.5 Translational Pathway and Impact Statement - Outline

Please describe the pathway envisaged to transfer the research findings originating from this research programme into effective applications in a real-world setting, with the goal of improving health and patient care.

Describe the potential beneficial outcomes and the resources that will make the plan feasible as well as the anticipated timescale for beneficial outcomes to be realised over the short, medium and long term. The word limit is **200 words.** 

### 5.6 References - Research Programme

A full description of the references cited for the <u>overall research programme</u>, inclusive of each research project proposed, should be provided. You can enter a maximum of <u>25 publications</u>.

Please enter references in the same format.

#### For peer-review publications:

Gallagher PA, Shoemaker JA, Wei X, Brockhoff-Schwegel CA, Creed JT. Extraction and detection of arsenicals in seaweed via accelerated solvent extraction with ion chromatographic separation and ICP-MS detection. Fresenius J Anal. Chem. 2001 Jan 1;369(1):71-80. PMID: 11210234.

### For book and printed source citations:

Farrell M, Gerada C and Marsden J (2000) *External review of drug services for the Eastern Health Board*. London: National Addiction Centre.

### For data citation<sup>19</sup>:

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

# 6. Training Programme Description (Training and Management)

### 6.1 Case for the doctoral training programme and training strategy outline

The training programme should have sufficient academic breadth to give trainees flexibility during their research education as well as exposure to international and inter-sectoral mobility as relevant to the research project. In

<sup>&</sup>lt;sup>19</sup> Please refer to FORCE 11 principles for further information <u>https://www.force11.org/group/joint-declaration-data-citation-principles-final</u>

Collaborative Doctoral Awards in Patient-focused Research (CDA) 2021 Guidance Notes

line with several documents describing the principles<sup>20</sup> for a more innovative and advanced doctoral training and HRB experience in funding and supporting PhD structured programmes, each consortium must provide a structured training programme with an appropriate balance between the training elements and sound research projects for each trainee which will benefit patient care and health.

- Describe why there is a strong need at national and/or international level to train individuals from a specific discipline/profession in this particular research thematic area;
- Please briefly outline how you propose to structure this doctoral programme in terms of training and professional development elements as outlined in the objectives of the call (page 5 of the Guidance Notes).

The word limit is 500 words.

### 6.2 Training Programme Support file

A file upload is available to include two attachments to support your Training Programme Description.

- Training programme summary chart. This is a **mandatory** component of the application form and should be a clear visual interpretation of the overall training programme. It is expected that this chart would be updated/revised at full application stage if required.
- Training Programme support file. This is an optional file upload in support of the Training programme and can be revised at full application stage if required

The maximum size is 2MB per file (.doc .docx .pdf).

# **Supporting documentation**

The following documents must be uploaded to complete the application:

- Letter(s) of Support for the Lead Applicant or Co-lead applicant(s) if in contract position(s) (Sections 3.2.2 + 3.3.2 + 3.4.2;
- Training Programme Summary Chart (Section 6.2).

The following is an optional upload:

• Training Programme Support File (Section 6.2).

http://www.thea.ie/contentFiles/national\_framework\_for\_doctoral\_education\_0.pdf

<sup>&</sup>lt;sup>20</sup> Principles of innovative doctoral training

https://euraxess.ec.europa.eu/sites/default/files/policy\_library/principles\_for\_innovative\_doctoral\_training.pdf; IUA PhD Graduate Skills Statement https://www.iua.ie/wp-content/uploads/2019/09/Graduate Skills Statement.pdf; National Framework for Doctoral Education

# **Submission of Applications**

The deadline for submission of complete applications is 17 December 2020 at 13.00.

- 1. After successful validation the Lead Applicant may submit the application. It will then be routed to the designated signatory at the Host Institution for their approval.
- 2. If a signatory rejects the application the Lead Applicant will be notified, along with any feedback the signatory has supplied.
- 3. The application can then be re-submitted; it will be returned to the signatory and will continue through the approval process as before.
- 4. On completion of the final approval by the Host Institution signatory, a grant application number is assigned to the application.
- 5. The application automatically gets submitted to the HRB through GEMS for consideration for funding.

Please note that the HRB will not follow up any supporting documentation related to the application. It is the responsibility of the Lead Applicant to <u>upload all supporting documentation prior to submission</u>. If the documentation is not received by the HRB on time, in the correct format or is not properly signed or submitted, the application will be deemed ineligible without further review.

The HRB reserves the right to reject any application that does not meet the terms of this call.

# **Appendix III - List of Regulated Health and Social Care Professions**

Regulated professions (listed in alphabetical order):

- Audiologists
- Clinical Biochemists
- Clinical Engineers
- Clinical Measurement Scientists
- Dentists
- Dieticians
- Health Psychologists/clinical psychologists
- Medical Practitioners
- Medical Physicists
- Medical Scientists
- Nurses and Midwives
- Occupational Therapists
- Orthoptists
- Paramedics and Advanced Paramedics
- Pharmacists
- Physiotherapists
- Podiatrists/Chiropodists
- Radiation Therapists
- Radiographers
- Social Care Workers
- Social Workers
- Speech and Language Therapists

# **Appendix IV - Resources/Useful Links**

**The Cochrane Library:** online collection of databases in medicine and other healthcare specialties which summarise and interpret the results of medical research. www.thecochranelibrary.com

**EQUATOR Network Library for health research reporting**: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies

http://www.equator-network.org/resource-centre/library-of-health-research-reporting/

#### CLINICAL RESEARCH INFRASTRUCTURES/SUPPORTS

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

Health Research Board Clinical Research Facility, Galway http://www.nuigalway.ie/hrb\_crfg/

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

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

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

Centre for Advanced Medical Imaging, St James' Hospital Dublin <a href="http://www.3tcentre.com/">http://www.3tcentre.com/</a>

Centre for Support and training Analysis and Research (CSTAR) http://www.cstar.ie

#### **BIOBANKING**

Council of Europe Recommendation of the Committee of Ministers to member States on research on biological materials of human origin (2016)

https://search.coe.int/cm/Pages/result\_details.aspx?ObjectId=090000168064e8ff

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

#### **ISBER Best Practices for Repositories**

http://www.isber.org/?page=BPR

#### Molecular Medicine Ireland Biobanking Guidelines

http://www.molecularmedicineireland.ie/resources/biobanking-guidelines/

#### NCI Best Practices for Biospecimen Resources (2016 version)

http://biospecimens.cancer.gov/practices/

#### **RESEARCH PRIORITIES & PUBLIC INVOLVEMENT IN RESEARCH**

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

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

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

European Patient Forum Value + Handbook (For Project Co-ordinators, Leaders and Promoters On Meaningful Patient Involvement) http://www.eu-patient.eu/globalassets/projects/valueplus/doc\_epf\_handbook.pdf

The James Lind Alliance Priority Setting Partnerships http://www.lindalliance.org/Patient\_Clinician\_Partnerships.asp

### **GENDER ISSUES IN RESEARCH**

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

Gender Toolkit in EU-funded research for examples and guidance http://www.yellowwindow.be/genderinresearch/downloads/YW2009\_GenderToolKit\_Module1.pdf

#### DATA MANAGEMENT AND SHARING and FAIR principles

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

#### UK Concordat on Open Research Data (July 2016)

http://www.rcuk.ac.uk/documents/documents/concordatopenresearchdata-pdf/

#### Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants\_manual/hi/oa\_pilot/h2020-hi-oa-datamgt\_en.pdf

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

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

FAIR at the Dutch centre for Life sciences <a href="http://www.dtls.nl/fair-data/fair-data/">http://www.dtls.nl/fair-data/fair-data/</a>

Registry of Research Data Repositories <a href="http://www.re3data.org/">http://www.re3data.org/</a>

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