Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie), using the templates provided. This system will close automatically at the stated deadline and timeline listed above. Applicants must read the “Detailed guidance on the Application Form”, appended to this document prior to completing the Application form.
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1. Introduction

The Health Research Board (HRB) *Strategy 2016 – 2020: Research. Evidence. Action.*\(^1\) sets out the aim to support the design, conduct and evaluation of healthcare intervention studies in order to improve health outcomes and health service delivery. Our current strategy commits the organisation to consolidate and build on progress made in constructing a coherent and integrated **clinical trials infrastructure** nationally (including facilities, coordination, research support, and networks) to deliver such interventions. The upcoming strategy 2021 – 2030 will build on the achievements made.

The Strategy recognises that healthcare interventions, including trials, are an essential step in translating research discoveries into improvements in health and health services. Patients benefit from having access to high quality clinical trials and overall outcomes are better in health systems that support clinical trials\(^2,3\). The economy also benefits from clinical trials by supporting enterprise development in areas such as pharma, medical devices and diagnostics; this in turn creates jobs and delivers significant benefits to the exchequer through direct and indirect savings.

Since 2010, HRB has been driving the growth of clinical trials in Ireland and putting in place the supporting infrastructure. In that period the HRB has invested over €100m in clinical trials infrastructures with the overall aim of facilitating clinical trials and clinical research in Ireland that can benefit patients, the health system and the economy.

Investment to date has been made in three Clinical Research Facilities (CRF) in Ireland, to provide the infrastructure (facilities, expert advice, research nursing support etc.) to conduct trials in any area of health. These include Wellcome Trust-HRB CRF at St. James Hospital in Dublin, HRB-CRF Cork at the Mercy University Hospital, and HRB-CRF Galway at University Hospital Galway. Individual Clinical Trial Networks (CTNs) have been funded to support communities of researchers in specific disease or health areas to develop and deliver a portfolio of trials. HRB-Clinical Research Coordination Ireland (HRB-CRCI) was established as a national resource to develop Ireland as a location for clinical trials by making it easier, more efficient and faster to set up and conduct multi-centre studies. Finally, HRB-Trials Methodology Research Network (HRB-TMRN) has been funded as a national network to improve the quality of trials by driving trials methodology research on the island of Ireland, advising researchers, and engaging in education and capacity-building in trial methodology.

In 2020, HRB is launching a number of calls for new investment in clinical trials infrastructure. In this next phase of investment, HRB will build on national investments and adopt a co-investment model with the Health Service Executive (HSE), universities and other stakeholders to develop a world-class clinical trials infrastructure with the capacity to deliver high-quality clinical trials.

As a key piece of the national clinical trials infrastructure investment, HRB is now launching a new national call for **Clinical Research Facilities/Centres (CRF/C)**. This is aimed at supporting the infrastructure, governance, and the skills and expertise to enable high-quality, safe, and compliant clinical trials and other interventions. This national investment in existing CRF/Cs is intended to transform the quality, capacity and accessibility of clinical trial infrastructure across Ireland.

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2. [https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0118253](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0118253)
3. [https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/414107](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/414107)
Applicants must show how this investment in CRF/Cs will improve patient access to trials and enhance and expand support to investigators who wish to design and deliver trials.

2. Clinical Research Facilities/Centres in Ireland

CRFs provide infrastructure, governance, and the skills and expertise to enable high quality, safe, and compliant research involving human participants, in particular clinical trials and other interventions.

**HRB-funded CRFs** typically provide supports and services that include:

- dedicated space for safe, high-quality trials (including early phase or Advanced Therapy Medicinal Product trials)
- support for study design, study coordination, monitoring etc.
- support the conduct of a portfolio of studies
- training for the local research community in clinical trials, having an impact on the expertise of local investigators.

The current HRB CRF awards enable salary support for core staff who are critical to operations but who cannot ordinarily charge their time to individual research studies e.g. the CRF Director, the CRF Programme Manager, and the Quality and Regulatory Affairs Manager. Not all other CRCs have the same range of supports. Staff numbers and roles vary across the CRF/Cs and encompass a wide range of expertise.

Typically, studies carried out within the CRF/Cs in Ireland are expected to bring external funding (either commercial or investigator-led) to cover the staff directly delivering the study and other costs.

In Ireland CRF/Cs may offer services and supports associated with Clinical Trial Units (CTUs) in the UK: “specialist units which have been set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies”. In the UK in particular registered CTUs “have the capability to provide specialist expert statistical, epidemiological and other methodological advice and coordination to undertake successful clinical trials”. Most CRF/Cs in Ireland would have to increase the scope of their activities to offer similar supports to investigators looking to conduct trials. **This new call is an opportunity for CRF/Cs in Ireland to consider the suite of supports they offer compared to a registered CTU, and use the opportunity to enhance supports available at a local level, particularly at the earlier stages of trial planning and design, including trial design and statistics support.**

2.1 Principles of the new HRB Investment in CRF/Cs

Principles of the new competitive CRF/C call have been developed with the Department of Health, Health Service Executive and other stakeholder input and include:

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• One named CRF/C from each Hospital Group (six adult and one paediatric) will be invited to apply.
• Applications must be being submitted through a recognised HRB Host Institution (academic partner).
• Applications will be submitted on behalf of a team, with two Co-Lead Applicants, one of whom must be the CRF/C Director, and another must represent the Hospital or Hospital Group.
• The focus of the call is firmly on supporting regulated and non-regulated clinical trials.
• HRB funding is not replacing existing financial support from the Host Institution/Hospital/other funding partner.
• Minimum co-funding equal to the level of HRB investment will be required from the academic partner, hospital group, individual hospital or other.
• Awards will range between €250k to €1m p.a. over five years; the number of awards will depend on funding and quality.
• Each CRF/C should request an additional budget to support feasibility work (associated with the National Clinical Trials Coordination Programme).
• Should one of the CRFs currently supported by the HRB not be successful a divestment process will be put in place.
• Applications will have to show how the team/personnel and infrastructure is aligned to support the portfolio for that CRF/C.
• Centres with lower levels of trial activity (based on registered clinical trials) will be expected to bid for lesser amounts.
• This call has been aligned with two other HRB calls: for cancer clinical trial infrastructure and the National Clinical Trials Coordination Programme, and successful awardees will be expected to work with/contribute to the national clinical trials infrastructure.

3. Aim and Objectives

The overarching aim of the HRB Clinical Research Facilities/Centres call is to support/upgrade national CRF/Cs to international standing, increase accessibility to trials for patients and healthy volunteers, and improve the supports available to investigators to drive an increase in investigator-led clinical trials. This call will require applicants to provide significant co-funding from the hospital and the academic partner.

Investments are intended to build on positive achievements within the system and improve the performance of the CRF/Cs against key metrics. The focus of the call is firmly on supporting regulated and non-regulated clinical trials.

5 While the minimum requirement for co-investment is 1€ for every 1€ invested by HRB, additional co-investment will be viewed favourably during assessment; the level of co-investment will be explicitly considered under the “Added-value of HRB investment” assessment criterion.
The purpose of this call is to improve patient access to high-quality, compliant, safe trials in Ireland and increase the number of high-quality clinical trials (investigator and industry-led) in Ireland to lead to improvements in clinical care through:

- Growing capacity for investigator-led clinical trials (with specific supports such as trial design aimed at supporting investigators)
- Contributing to operations to ensure quality/safety (Operations /Quality and Regulatory Affairs Manager/Director of Nursing/Data Lead ...)
- Supporting training of the investigator community
- Leveraging local research strengths
- Stimulating and formalising further co-investment infrastructure.

The investment will potentially provide funding for each of the seven named CRF/Cs that align with the Hospital Groups (six adult and one paediatric).

4. Scope

HRB investment through this competitive call for CRF/Cs should enable more stable operations, deliver clear added-value, and a strategic outlook for the next 10 years. Successful applicants must demonstrate how CRF/Cs will work to support and deliver clinical trials and interventions that can address health and social care needs in Ireland, with a particular focus on developing a portfolio of investigator-led clinical trials.

In scope:

- Increased supports for trial design and biostatistics support at local/regional level
- Enhanced quality/safety systems/management
- Enhanced operational capacity, including the ability to capture relevant metrics
- Building capacity in skills needed to conduct clinical trials in Ireland

HRB expects that each CRF/C is able to report relevant metrics regarding the delivery of trials within the portfolio, and this call should be used to establish/enhance this capacity at the CRF/C level where this does not currently exist.

HRB expects that basic trial design support (including biostatistics) should be available at the local CRF/Cs, and this call should be used to establish/enhance this capacity at the CRF/C level where this does not currently exist. This should provide support to investigators at the early stages of planning and designing trials. A CRF/C should be able at a minimum to support the design of a Randomised Controlled Trial, and support the development of a statistical analysis plan\(^6\) for the purposes of securing funding. Such consultancy work is typically carried out without funding available through an individual trial and may require core funding. Throughout the lifetime of the trial, ideally CRF/Cs should have biostatistics resources available to support trial analysis and reporting, with funding provided from external sources.

\(^6\) It is planned that future applications to HRB’s DIFA scheme will require a draft SAP at full application stage.
CRF/Cs will be expected to refer investigators to HRB-TMRN where proposed trials design involves novel or complex methodology. CRF/C should engage with HRB-TMRN for future training in trial design, and in considering how best to build up capacity in this area at local level.

Activities **must** complement and coordinate with other national investments (e.g. trial networks, HRB-TMRN, national clinical trials coordination programme, National PPI Network). Two other HRB calls for cancer trials infrastructure and National Clinical Trials Coordination Programme have been closely aligned with this call to enable this.

**CRF/C Portfolio**

HRB is open to supporting a wide spectrum of clinical trials, regulated and non-regulated, across all disease areas and phases. It is expected that the portfolio of trials for each CRF/C will depend upon the settings available, clinical specialties with research interests in the Hospital/Hospital group, linked trial networks, existing industry partnerships, and local infrastructures. Each CRF/C will have differentiated offerings and it is expected that they will articulate this in their bid. Applications will have to show how the team/personnel and infrastructure is aligned to support the portfolio for that CRF/C, whether for early-phase or Advanced Therapy Medicinal Product trials in a dedicated in-patient setting, trials on hospital wards, and/or trials in a community setting. It is intended that a base-line level of supports and services should exist at all local CRF/Cs. Where a CRF/C cannot support an intended trial, they should re-direct investigators towards an appropriate infrastructure; this should also happen if an investigator approaches the National Clinical Trials Coordination Programme.

**Out of scope:**

This scheme will **not** provide funding for

- Establishing new CRF/Cs or new premises, including building work, fit-out of buildings, or major pieces of equipment
- Support for clinical research outside of clinical trials such as biobanking and observational studies
- Individual trials (definitive interventions or feasibility studies)
- Applications from individuals applying for, holding, or employed under a research grant from the tobacco industry.

**5. Eligibility**

For the purposes of this national call, one CRF/C per Hospital Group, plus Children’s Health Ireland will be invited to submit an application for investment. Eligible CRF/Cs are located at:

1. Wellcome Trust-HRB-CRF at St. James Hospital in Dublin (hosted by Trinity College Dublin)
2. HRB-CRF Cork at the Mercy Hospital and Cork University Hospital (hosted by University College Cork)
3. HRB-CRF Galway at University College Hospital Galway (hosted by the National University of Ireland Galway)
4. UCD CRCs at The Mater Misericordiae University Hospital and St Vincent’s University Hospital (hosted by University College Dublin)
5. Royal College of Surgeons in Ireland CRC at Beaumont Hospital (hosted by Royal College of Surgeons in Ireland)
6. The Health Research Institute Clinical Research Support Unit at Limerick University Hospital (hosted by University of Limerick) and
7. Children’s Health Ireland (various academic partners).

Applications must be submitted through a recognised HRB Host Institution (academic partner). Applications will be submitted on behalf of a team, with two Co-Lead Applicants, one of whom must be the CRF/C Director, and another must represent the Hospital or Hospital Group.

5.1 Minimum requirements for all applications

- **HRB funding is not replacing existing financial support** from the Host Institution/Hospital/other funding partner.
- **Minimum co-funding required of €1** (from academic partner, hospital group, individual hospital or other) for every €1 HRB investment.
- Team member(s) with responsibility for growing the investigator-led portfolio of trials.
- List of registered clinical trials approved by CRF/C in 2017/18/19/20, including study metrics.
- Published process for access to supports, with assessment criteria, and clear cut-off dates for access to supports where applicable.
- Published process for peer review of any studies which do not come with external funding.
- Policy on the procedure and criteria for stopping trials.
- Charging model/list of fees provided for industry studies.
- All CRF/Cs receiving HRB funding will be expected to support, and to contribute to, the national clinical coordination feasibility programme, and resources should be assigned for that purpose.

5.2 Eligibility of Applicant Team

The Applicant Team should be based on a pre-existing group instrumental in the oversight and running of the current infrastructure, plus any new members in one of these roles under the award.

The applicant team will have two Co-Lead Applicants for the CRF/C call, at least one of whom must be the current Director of the CRF/C. The other Co-Lead Applicant must represent the Hospital or the

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7 Associated charities or Foundations
8 While the minimum requirement for co-investment is 1€ for every 1€ invested by HRB, additional co-investment will be viewed favourably during assessment; the level of co-investment will be explicitly considered under the “Added-value of HRB investment” assessment criterion.
9 Trials that are not registered will not be considered
10 On associated CRF/C website, the document needs to be visible to the public
11 Note: at time of application these charging models/list of fees are not expected to be the same for each CRF/C
Hospital Group where the CRF/C is located at a senior level. **The Co-Lead Applicants will have joint overall responsibility for delivery of the objectives of the CRF/C.**

The division of responsibilities between the Co-Lead Applicants should be clearly outlined in the application. The CRF Director will serve as the primary point of contact for the HRB during the review process and the duration of any subsequent contract. This individual will also have primary fiduciary responsibility and accountability for carrying out the activities within the funding limits awarded and in accordance with the terms and conditions of the HRB.

Up to 10 Co-Applicants can be listed. The Co-Applicants have a well-defined, critical and substantial role in terms of assisting the Co-Lead Applicants with the leadership and management of the CRF/C. The Deputy Director must be included in the list of Co-Applicants. Ideally the Co-Applicant list will include individuals in the CRF/C leading on operations, and the Chairs of the Scientific Advisory Board and/or Public Advisory Board where these exist. It is suggested that an individual in the linked academic institution facilitating the integrations between hospital site and university, and enabling sponsorship is included.

HRB expects that the Co-Lead Applicants and Co-Applicants have a clear remit with respect to strategic and scientific oversight, and operational and administrative responsibility for performance.

### 5.2.1 Eligibility Criteria for Applicant Group

The Co-Lead Applicant (CRF/C Director) must:

- Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland (the “Host Institution”) as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable or
- Be a contract researcher recognised by the Host institution as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible, or
- Be an individual who will be recognised by the Host Institution upon receipt of award as a contract researcher as defined above. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

The Host Institution (HI) for the HRB award is a HRB recognised host institution. It is normally that of one of the Co-Lead Applicants, but it may be another organisation/institution designated by the research team, where it is clearly justified. An up to date list can be found at [http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/](http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/). The Host Institution agrees to provide support for the management of multi-site trials, including e.g. agreeing collaboration agreements between, and managing payment to, partner institutions.

A Letter of Support must be provided by the Host Institution and Hospital/Hospital Group and must detail the supports provided to date and to be provided during the term, as well as the income to be counted as co-investment (See Detailed Guidance on the Application Form, Section 6.4).

Note: where an applicant fails to meet eligibility criteria, or the scientific and strategic remit of the application is outside the scope of the scheme, the application will be deemed ineligible and will not be accepted for review. The HRB will contact the Host Institution and Co-Lead Applicants in the event that this situation arises.

6. Funding and Duration of Awards

6.1 Funding Available

Awards will range between €250k to €1m p.a. over five years. The award will predominantly offer support for operational costs such as salary for core staff members in the CRF/C. New roles should add clear value to the existing team and address gaps for supporting investigator-led trials, in particular trial design and biostatistics support where these are currently not available at local level.

It is recognised that CRF/Cs have a spectrum of needs, requirements, ambition, and absorptive capacity for additional funding, therefore different levels of investment are expected. The funding request for each staff position should be clearly justified in terms of added value for the CRF/C. Each position requested should make sense in terms of the scope of the role, and when it will come on-stream. It is possible that the Panel will recommend funding for some positions but not others.

We expect the following:

- Up to seven awards, quality permitting, to improve equity of access for patients to trials nationally.
- Average HRB investment in each currently HRB-funded CRF will not increase: either stay at same level, decrease or divest.
- Divestment provision for CRFs currently funded by HRB should an award not be recommended.
- Funding cannot displace core institution/hospital funding; existing investment can be captured as matched funding.
- Centres with lower levels of trial activity (based on registered clinical trials between 1 Jan 2017 and 31 Dec 2020) will be expected to bid for lesser amounts.
- Recruiting experienced (senior) team members can be slow, so centres with low levels of activity cannot be expected to suddenly expand their team if current levels of trial activity are low.
- Staffing requests should reflect the research capacity within the community it serves.
- HRB will reserve the right to offer a (significantly) reduced award on the advice of the Panel.
- Investments will be reviewed after three years. Where a reduced award was initially made increases may be made in the last two years subject to satisfactory progress\textsuperscript{12}.

\textsuperscript{12} Within the €5m cap per award
HRB funding will be up to a maximum of €5,000,000 per CRF/C award, inclusive of overheads (30%). The duration of the awards will be 60 months. **Funding is not provided for individual trials (definitive interventions or feasibility studies).** Trials and interventions are expected to provide funding, e.g. industry-sponsored, charity funded or through competitive means, such as the HRB DIFA scheme.

An **additional budget** per CRF/C should be requested to support feasibility work (associated with the national clinical trials coordination programme). Personnel should be appropriate to delivering the feasibility programme and may differ in configuration across the CRF/Cs. Funding can be requested at a level not higher than 0.2 FTE Data Manager or equivalent and 0.5 FTE Research Nurse or equivalent (not expected to exceed €70,000 p.a. for all personnel involved, inclusive of overheads). These resources must be clearly identified within the budget for the feasibility programme and requested supports justified accordingly.

Co-investment is a minimum requirement of the call, and the level of co-investment presented will be reviewed by HRB along with other eligibility requirements. **HRB expects the majority of income committed for the purposes of co-investment to be in the form of salaries for individuals working in the CRF/C, with some running costs also allowable.**

We expect the level of co-investment proposed to broadly match/exceed the requested HRB budget in any given calendar year, i.e. where €500,000 HRB budget is requested in Year 2, a similar level combined co-investment by (HI/Hospital/Associated charity) or more is expected in Year 2. Over the five-year period of the award the total confirmed co-investment must equal or exceed the requested HRB budget.

Responsibility will lie with the Host Institution/Hospital to ensure the matching funding requirements are met. In all cases the Host Institution/Hospital contribution should be justified, measurable and verifiable. All documentation relating to matched funding provided to the HRB-CRF/C by the Host Institution/Hospital must be available for audit purposes if required.

*The Host Institution will be required to confirm that costs included as matched funding are not covered by grants from other Government sources outside of the HEA block grant.*

It must be clear that HRB investment has added value. **HRB funding is not intended as a replacement for existing financial support from elsewhere.**
6.2 Eligible costs

It is expected that support for biostatistics/trial design expertise at local level will form part of the budget request should these not be funded from alternate sources. Public and Patient Involvement activities are expected to form part of the work of the CRF/C.

Eligible costs include:

- **Contributions to Personnel costs**: as appropriate and justified given the scale and scope of CRF/C activities (e.g. Trial design expertise, Data Lead, PPI Coordinator, Business Development role, QRAM, contributions to Director salary, CRF Operations Manager, Director of Nursing, Administrative support).
- **Running costs**: Contribution towards costs required to run the CRF/C for example travel, training, legal costs, consultancy fees, licences, IT-related costs etc. training and exchange opportunities to build capacity, PPI costs.
- **Dissemination and knowledge exchange costs**: e.g. outreach events: Communication/promotion costs should be captured here, for promotional events, production of brochures.
- **Equipment**: small equipment costs only – do not expect in excess of €20,000.
- **FAIR Data Management**: for example Data Steward consultancy to support CRF/C activities.
- **Overhead contribution** of 30% TDMC*

*Total direct modified costs (excluding equipment or fees). Overheads on the award will be paid directly to the Host Institution. While overheads may be distributed between the HI and Hospital partners by mutual agreement, any portion of the overheads agreed as payable to the Hospital will be routed through the Host Institution.

**Quality permitting, up to seven awards will be made in this round.** Awards must commence in January 2022. Applicant teams can request funding for costs incurred from January 2022 to December 2026.

Funding will be awarded on a claims-made basis. Should the budget allocation for a period not be claimed in full, the balance cannot be carried over and will be lost to the award. Therefore, it is important when developing the budget that applicants plan carefully in order to enable draw-down of the full amount awarded.
7. Coordination with other trial infrastructures

As we enter a new phase of investment in national clinical trials infrastructure, it is critical that coordination and synergies are enhanced across the system to maximise the value of this investment.

To this end, successful awardees will be expected to work with other clinical trial infrastructures within the national system to collectively improve patient access to clinical trials, and to enhance supports for investigator-led trials in Ireland. Expectations for the collaborative nature of the investment in CRF/Cs will be underpinned through special contractual conditions in relevant grant contracts and will be a core element in ongoing assessment of grant performance of any subsequent award.

Collaboration with other infrastructures nationally

Applicants firstly must describe how they will work with other CRF/Cs in the context of a national network. Additional resources are being provided as part of this call to work with and contribute to the National Clinical Trials Coordination Programme. In particular applicants must describe how they will contribute to, and lead as appropriate on National Clinical Trials Coordination Programme Working Groups or programmes of work, and to ensure the adoption of these outputs within their CRF/Cs to deliver streamlined processes across all CRF/Cs.

Personnel resourced to deliver the feasibility programme provide an underpinning link between the clinical trials infrastructures and the national coordination programme. They are responsible for providing local data and information from the clinical trials infrastructure to the national coordination programme and for leading local implementation of measures to support national alignment. These personnel will have prioritised reporting lines to the Lead of the National Clinical Trials Coordination Programme to facilitate this, in addition to their own employer.

CRF/Cs are expected to have, or through this award to establish, basic trial design support (including biostatistics) at the local level to aid investigators at the early stages of planning and designing investigator-led trials. Such consultancy work is typically carried out prior to funding being available through an individual trial and may require core funding. Throughout the lifetime of the trial, ideally CRF/Cs should have biostatistics resources available to support trial analysis and reporting, with funding provided from external sources. CRF/Cs will be expected to refer investigators to HRB-TMRN where proposed trials design involves novel or complex methodology. CRF/Cs awarded through this call will also be expected to work closely with HRB-TMRN throughout the term of the CRF/C award in building national capacity in relation to trial design, and availing of education opportunities in trial methodology for their team.

CRF/Cs must also clearly show how they will support and align with HRB-funded Clinical Trial Networks, including for cancer, throughout the term of the award. CTNs should be able to access services in CRF/Cs to enable them to design and deliver (externally-funded) trials. Cancer trial delivery Clusters may work with CRF/Cs for enhanced governance, trial design, recruitment of staff per trial etc. Applicants must demonstrate how synergies can be maximised in working with clinical trial networks.
International coordination

Applicants should describe how they work with and are coordinated with other relevant international structures (as relevant to their portfolio), such as but not limited to, the UK CRF Network, and ECRIN.

A Letter of Support/Infrastructure Agreement Form from all relevant clinical research infrastructures will need to be provided at time of application, clarifying how they will work with the CRF/C for the term of the award.

8. Public and patient involvement (PPI) in research

The HRB Strategy 2016-2020, Research. Evidence. Action., refers to Public and Patient Involvement (PPI) as a core principle and contains the commitment to strengthen and develop PPI within the HRB and in HRB-supported projects and programmes. The HRB is the first public funding agency in Ireland to do so. The development of the next HRB strategy is progressing and putting the public at the heart of the research that the HRB funds is emerging as a theme. Therefore, the HRB expects all funded clinical trial infrastructures to support PPI.

The HRB is using the definition of PPI proposed by INVOLVE: Research carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them. The HRB promotes the active involvement of members of the public in the research that we fund. Public involvement 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.

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

PPI contributors should be actively involved and part of decision making. Involving members of the public in research can improve quality and relevance of research. 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 or patients
- identify a wider set of research topics than if health or social care professionals had worked alone

• help you increase participation in your research by making it more acceptable to potential participants.

In addition to improving relevance and quality of research, it ensures that research is influenced by broader principles of citizenship, accountability and transparency. PPI is an ethos as well as a practice. It should be context-specific and should aim to ensure that all voices are heard. Where members of the public or patients are involved, they must be compensated for their time and contributions.

Applicants are asked to describe how the CRF/C will support researchers’ PPI activities during the development of an application and during the conduct of a trial.

**PPI should play a critical role in clinical trials. If there is currently no PPI strategy within your CRF/C this is an opportunity to develop an approach to embed PPI within the work of your CRF/C.** The HRB together with the Irish Research Council are currently inviting an application for a National PPI Network, with sites across Ireland. Coordination of activities between the National PPI Network and individual CRF/Cs is expected.

9. Application and assessment process

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 at each stage of the process.

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) ([https://grants.hrb.ie](https://grants.hrb.ie)). **GEMS will close automatically at 1pm on Tuesday 19 January 2021.** The application must have been reviewed and approved by the signatory approver at the research office (or equivalent) in the host institution before it is submitted to the HRB. Therefore, applicants should ensure that they give the signatory approver enough time before the scheme closing date to review the application and approve it on GEMS. Please note that many host institutions specify internal deadlines for this procedure.

The **HRB Gender Policy** came into effect on 1 June 2016. In line with international best practice the HRB has a responsibility to support all people to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. To ensure fairness and equality to all applicants, each funding application received will be assessed as outlined in the call guidance documentation for that particular funding round.

A key objective of the HRB is to strive for gender balance in Irish health research. To ensure gender balance in decision-making, the HRB aims to reach the international best practice target of 40% of the under-represented gender in all HRB Panels where possible. Gender will also be considered when appointing the position of Panel Chair. As part of this application, applicants are asked to describe whether gender balance been taken into account in the management structure/at decision-making levels.

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CRFs should ask researchers as part of their consultation processes to consider potential gender and/or sex differences that may arise within the context of a trial, which should be accounted for during design, conduct, analysis and dissemination of the research.

9.1 Application process

HRB will invite the seven above-named CRFs to submit an application. The application will be in the form of a strategy statement and business plan in a template format provided by the HRB on GEMS. Applications will describe the nature, scope and direction of the next phases of development of the CRF/C, and specifically the added-value of HRB investment (2022-2026). Details on resources required (HRB and non-HRB funded), as well as income and expenditure projections will be requested. The submitted application will outline the vision for future development of the CRF/C. It should include short and mid-term objectives within the term of funding, as well as longer-term objectives (post 2026). Applicants must describe how they will build on and consolidate work to date. Importantly, the CRFs must clearly describe how they will work with each other and with other HRB investments in the system, such as coordination of clinical trials, clinical trial networks and the HRB-TMRN.

Applicants will also be asked to submit a video showing the physical infrastructure(s) in the CRF/C. Further details on the requirements is provided in the Detailed Guidance on the Application Form.

It is currently planned to have a virtual Q&A session for applicants; to enhance consistency in submissions to HRB.

Submitted applications will first be checked for completeness. HRB staff will perform an eligibility check against the minimum requirements for this scheme:

- Financial management capacity
  ✓ Existing level of investment by institution and/or linked charitable organisations is maintained or increased
  ✓ Minimum co-investment requirements confirmed for term of award
- All listed minimum requirements including,
  ✓ Published process for access to the CRF/C supports
  ✓ Published process for peer review of studies that do not have external funding
  ✓ Policy on the procedure and criteria for stopping trials
  ✓ List of registered clinical trials approved by CRF/C in 2017/18/19/20
  ✓ Study metrics (Excel template provided on GEMS)
  ✓ Submitted charging model/List of fees for industry studies
  ✓ Identified team member(s) with responsibility for growing the investigator-led portfolio of trials
  ✓ Resources allocated to supporting (HRB CRCI) feasibility programme.
Only complete, eligible applications will undergo a Panel assessment process as follows:

9.2 Panel review

There is a single step review by a Selection Panel, with no additional written peer review. An international Panel will be established comprising an independent Chair and three to six members. The Panel will have relevant expertise including Operations, Business Development, and CRF Director experience. It is envisaged that some will have served on previous HRB Panels.

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 Panel 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 Panel 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.

Interview

The Co-Lead Applicants and key team members from each team will be invited to attend an interview. Initial comments or questions from the international Panel will be provided to the Co-Lead Applicants prior to the interview. This will provide the Co-Lead Applicants and their team with an opportunity to address the key comments and suggestions, during the interview. The interview will begin with a short presentation by the applicant team where the applicant team should aim to address the main concerns raised by Panel members, followed by a Q&A session. A number of questions aligned with the assessment criteria will be asked of all applicants during the Q&A session, to aid comparisons between the applications.

More details on the interview will be provided to the applicant teams closer to the time. The names of the Panel members will be provided to the candidates a few days before the interview meeting.

The Panel will make a recommendation to the HRB at the end of the meeting.

9.2.1 Assessment criteria

The reviewers will assess all applications based on the following criteria and must score well in all areas.

- **Added-value of HRB investment**
  - Additional impact of HRB investment convincing
  - CRF/C role in delivering objectives of HRB call is clear
  - HRB support complements and leverages additional HI and Hospital investments
  - Evidence of support for, and contribution to, other HRB-funded infrastructures

- **Clarity and strength of Business Model**
  - Vision, scope and strategic objectives of the CRF/C are clear and appropriate
  - Spectrum of activities/supports is appropriate in serving the relevant researcher base
  - Governance and management arrangements are appropriate
Clear, strong links with HI and Hospital evident in governance arrangements
Evidence local expertise/thematic strengths have been exploited in model

- **Quality of the proposed Business plan**
  - Business plan will deliver strategic objectives of CRF/C, including objectives of HRB call
  - Investigator supports are developed as appropriate
  - Proposed work is prioritised and phased appropriately
  - Budget and resource details proposed are clear and appropriate
  - Risks clearly identified and appropriate strategies proposed to minimise their impact

- **Quality of Team**
  - Leadership from Senior Management appropriate
  - Credibility, synergies, and suitability of key staff members evident
  - Roles and responsibilities of proposed team are clear
  - Proposed team can deliver on strategic objectives

The criterion of “Added-value of HRB investment” is a *Pass/Fail criterion*. Should any application score “Poor” against this criterion, regardless of how highly other areas score, the Panel will recommend that HRB does not proceed with any investment.

In addition, applicants should be aware that where the Panel raises serious concerns regarding aspects of the proposal, e.g. related to governance, and these issues have not been addressed to the satisfaction of reviewers, such applications will not be supported.

### 9.2.2 Potential outcome of review

Based on the outcome of this review process, the HRB will seek Board approval for proposed recommendations. The possible outcomes of the approval process for each CRF/C submitting an application are:

a) HRB agree to fund the proposal as submitted
b) HRB offers to fund aspects of the application, potentially subject to conditions
c) HRB does not proceed with any investment.

Should the recommendation be made that HRB does not proceed with an investment in a previously funded HRB CRF, there will be a divestment provision for 2022 and 2023, to allow an orderly wind-down of HRB support.

*Any HRB investment to support the feasibility programme of the National Clinical Trials Coordination Programme will be contingent on the Panel recommending an award to the CRF/C.*

A written Panel report will be sent to the applicants following the interview Panel. This will contain feedback and any conditions where funding is recommended. The applicants will have a specified period to consider the Panel report and respond accordingly.
The Panel reports and applicant responses 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.

The HRB reserves the right to modify the review process. Applicants will be notified of any relevant modification to the review procedure.

10. HRB Oversight and monitoring

10.1 HRB Expert Advisory Group

For independent oversight and strategic leadership, the HRB will appoint a Clinical Trials Infrastructure Expert Advisory Group to oversee our investments in Clinical Trials Infrastructure from 2021 onwards.

The Expert Advisory Group will be established to help guide the HRB and the clinical trials community to:

- work towards integrating clinical trials within the health system to ensure that they are delivered as part of usual care,
- raise the standards of the clinical trials environment and their conduct in Ireland whilst,
- safeguarding the HRB’s investment of approximately €60 million in Clinical Trials Infrastructure over the next five years.

The Expert Advisory Group will work with the HRB to review performance of all clinical trials infrastructures on an ongoing basis and will be instrumental in implementing corrective action where needed.

10.2 Award monitoring

Mandatory metrics will be established for successful bids, which will be used by HRB to monitor progress for individual trials, as well as in providing supports/services to investigators. Clear reporting of metrics will be a pre-requisite for continued funding, which will be monitored on an annual basis and evaluated at an interim point. Mandatory metrics will include information about e.g. the number and type of clinical trials, study start up, registration, recruitment levels - time to target vs. global recruitment, reporting, changes to clinical guidelines/practice, research articles, educational resources, reports, policy briefs and other relevant documents.

Awardees will have to report on activity as part of the national feasibility programme of the National Clinical Trials Coordination Programme (for which there is additional budget). This will form part of the contractual obligations to the HRB. Awardees will also be expected to report activity in relation to participation in or leadership of National Clinical Trials Coordination Programme Working Groups, and adoption of the outputs. Furthermore, awardees will be expected to report activity in relation to work with other clinical trial infrastructures, including HRB-TMRN, HRB-funded clinical trials networks, and the National PPI Network.
A scientific and strategic progress review will be undertaken by an international Panel of experts at approximately 36 months.

11. Trial Registration and Reporting

The HRB is a signatory of the AllTrials campaign (http://www.alltrials.net/) and supports the aim of having all trials registered and all results reported. We extend this ambition to all interventions funded by the HRB, as well as trials delivered by networks funded by the HRB. Unregistered and unreported interventions are unethical and cause harm because 1) the work may be repeated, 2) a metaanalysis of published results will be skewed, potentially leading to flawed clinical decisions and 3) participants have a legitimate expectation that results will be published.

Therefore, and aligned to the HRB Clinical Trials and Interventions Research Governance Policy, we will require all interventions carried out by HRB-funded CRF/Cs to be registered in a publicly accessible register prior to initiation of the study, as part of their contractual obligations. Results must be reported on the register within twelve months of completion of the intervention. The HRB also expects that results (positive and negative) of the intervention will be submitted for publication. These results must be posted to the results section of the clinical trial registry where the trial was originally registered.

12. GDPR

The General Data Protection Regulation (GDPR) came into force on 25 May 2018. As a result the applicant team will be asked through GEMS to consent 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 Panel 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. Panel 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 consent that 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 data retention

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.

13. Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 July 2020</td>
<td>Applications for CRF/C open</td>
</tr>
<tr>
<td>19 January 2021</td>
<td>Deadline for submission of applications</td>
</tr>
<tr>
<td>January - March 2021</td>
<td>Application review process</td>
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<tr>
<td>Late March 2021</td>
<td>Interview panel meeting</td>
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<tr>
<td>June 2021</td>
<td>Board approval</td>
</tr>
<tr>
<td>July - November 2021</td>
<td>Contracting for successful awards</td>
</tr>
<tr>
<td>January 2022</td>
<td>Awards start</td>
</tr>
</tbody>
</table>

The deadline for submission of applications through GEMS is Tuesday 19 January 2021 by 13.00 pm.
14. Contacts

For further information on the HRB Clinical Research Facilities/Centres call contact:

**Dr Susan Quinn**
Project Officer
Health Research Board
e squinn@hrb.ie
t +353 1 2345 139

**Dr Caitriona Creely**
Programme Manager
Health Research Board

*It is the responsibility of the Co-Lead Applicants to upload all supporting documentation to GEMS prior to submission. If the documentation is not received by the HRB on time, in the correct format or is not properly signed or submitted, the application may be deemed ineligible without further review.*

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

*The HRB’s procedure for appealing funding decisions is available at http://www.hrb.ie/funding/funding-schemes/before-you-apply/relevant-policies/*
Appendix I: Detailed Guidance on the Application Form

Only registered users of the GEMS system can apply for grants. In order to submit an online application to the HRB, applicants are required to register at the following address: https://grants.hrb.ie

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

The Lead Applicant must create the application, but it can then be jointly completed with the named Co-Lead and Co-Applicants.

- Applications will be submitted on behalf of a team, with two Co-Lead Applicants, one of whom must be the CRF/C Director, and another must represent the Hospital or Hospital Group.
- The Lead Applicant (CRF Director) must take on the role of submission to GEMS; their CV and contact details will be pulled through from GEMS.
- The Co-Lead Applicant (Hospital) must enter their details manually. Both Co-Lead Applicants must review and approve the application prior to submission.
- Lead Applicants can register on GEMS and they will receive an email to confirm their registration and log in details. The Lead Applicant can then add information on their contact and CV details in ‘Manage My Details’ section of GEMS.
- Lead Applicants previously registered on GEMS can login to GEMS and update any information regarding their contact and CV details in ‘Manage my details’.

Once logged in to GEMS applicants are taken directly to the Home page which is the starting point to create a new Grant application. Please select the HRB Clinical Research Facilities/Centres (CRF/C) 2021. Further details for completing each of the main sections of application form is provided below:

**Host Institution**

The Host Institution (HI) for the HRB award is a HRB-recognised host institution. It is normally that of one of the Co-Lead Applicants, but it may be another organisation/institution designated by the research team, where it is clearly justified. An up to date list can be found at http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/. Identify a Host Institution from this list and type it into GEMS in full (do not use acronyms such as UCD, TCD, NUIG). Once you have entered the first 3-4 characters of the HI, you will be assisted with auto-select options. It is important that the HI name is entered accurately and in full, as an incorrect entry may result in delays in attaining HI approvals.

**Signatory Notification (within Host Institution)**

Once the Host Institution is selected at the initial stages of application creation this will allow the Lead Applicant to notify the authorised signatory (Dean of Research or equivalent person authorised to endorse research grant applications for the Host Institution) in that Host Institution of the Lead Applicant’s intention to submit an application to the HRB CRF/C 2021 call. The signatory’s details are pre-populated in the system so the applicant just needs to click ‘NOTIFY’ within GEMS. We recommend that you notify the HI signatory of your intention to apply as soon as possible in the application process. The signatory will receive an email from GEMS with the name and email details of the Lead Applicant and if they have any queries or clarifications they can engage directly to resolve them with
the Lead Applicant. The HI signatory must confirm their willingness to participate as HI for the application through GEMS and once they do this a PDF of the application will be available for them to review with a view to them ultimately approving the final version for submission to the HRB.

Section 1: CRF/C Overview

1.1 Named Director (Lead Applicant):

1.2 Deputy Director (If not formally appointed, please identify the person who will act on behalf of the Director should they be absent or unable to perform their duties):

1.3 Name of CRF/C:

1.4 Award Duration and Start Date

*Please note that awards are 60 months in duration and all awards are expected to commence during January 2022. Please indicate the anticipated start date. The earliest start date for awards is 01 January 2022.*

1.5 CRF/C description

This should be a succinct summary of the proposed CRF/C activities to be funded from this award and how they complement activities funded from other sources. The aims of the CRF/C should be conveyed with clarity. The objectives of the CRF/C and what the work is expected to establish should be described. This should provide a clear overview of the CRF/C and should set it within the national context. The word limit is 500 words.

1.6 Lay summary

This lay summary should describe what you propose to do, say why you think it is important to complete this work, and how it will be done. The difference is that it needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience. The lay summary may be used when providing information to the public with regards to the variety of research/supports funded by the HRB and may be published on the HRB website. The word limit is 300 words.

1.7 History of the CRF/C

Please provide a brief history of the CRF since its establishment. Include details of the position of the CRF in the Irish health research ecosystem. The word limit is 500 words.

1.8 Infrastructure

Please describe the levels of personnel, facilities and infrastructure in the CRF/C to carry out clinical trials.

Please summarise supports from the Host Institution/ Hospital/Associated charity or Foundation since the establishment of the CRF/C such as e.g. capital funding, funding for equipment and fit-out, support for financial reporting, HR etc. Please give an overview of salary supports and other direct financial supports provided from the Hospital and Host Institution, and indicate duration of the support.
HRB CRF/C 2021 Guidance Notes

Please detail arrangements with local hospitals and local/regional/national infrastructures regarding access to expertise, facilities or space.

Please describe what is working well at present, current challenges, and what will change over the term of investment should this application be successful.

The word limit is 500 words.

1.9 Video tour of facilities
Please provide a link to a video of no more than 5 minutes featuring the existing facilities. The video should entail a walk-through and brief overview of the facilities, and any underpinning infrastructure. Please note that the Panel will be interested in substance/content rather than in production/style.

1.10 Upload of floor plan(s) (optional)
You may upload the floor plan of the facilities (2 A4 pages max).

Section 2: Business Model

2.1 CRF/C Strategy
Briefly describe the strategic position of the CRF/C. Detail key opportunities and strategic challenges for the CRF/C.

Please state the vision and mission of the CRF/C, that includes the investment term 2022-2026 (approximate 5-year horizon expected). Please describe strategic objectives aligned with the vision and mission, to include the proposed term of HRB investment 2022-2026.

The word limit is 300 words.

2.2 Governance and Management
Please describe the governance arrangements for the CRF/C. Please provide details about any reporting relationship with the HI/hospital groups and external governing bodies as appropriate. Include details of Governance Board, Scientific Advisory Board and any other committees as applicable (role/membership/frequency of meetings).

Please describe what is working well at present, current challenges, and what will change over the term of investment should this application be successful.

The word limit is 300 words.

2.2.1 Governance Organogram Please upload an organogram depicting the governance structure that is currently in place.

Awardees will also be expected to cooperate fully with any HRB Clinical Trials Infrastructure Expert Advisory Group. This expert advisory group is anticipated to assist HRB in the strategic oversight and performance monitoring of the Infrastructures, Networks, and Interventions portfolio.

The word limit is 300 words.
2.3 CRF/C operations

Please describe how the current organisational structure and management capability is appropriate to the stage and scale of the proposed initiative. Please identify the person who will act on behalf of the director should he/she be absent or unable to perform his/her duties.

Has gender balance been taken into account in the management structure/at decision-making levels? (please refer to HRB’s Gender Policy16). Has the CRF/C a Gender policy, or a broader policy on Equality, Diversity and Inclusion?

Explain how the CRF/C currently scales resources according to demand for support. Describe processes for making decisions on scientific direction and allocation of resources (e.g. selection of studies).

Briefly describe key policies and processes. This should include but is not limited to study selection, study costing, resource allocation, quality systems, pharmacovigilance, data management, and information systems. You may embed links to key SOPs/policies.

Please note the results of recent audit reports, if available.

The word limit is 500 words.

2.3.1 Please provide a link to the CRF/C published process for peer review of any studies which do not come with external funding.

2.4 CRF/C Financial Management

Please provide details about the current financial management processes to manage CRF/C income and expenditure. Please include information on accounts to be used, processes such as invoicing, and processes to enable income and expenditure to be reported on an annual basis. Please comment on the appropriateness of the system and any planned changes.

The word limit is 200 words.

2.5 Business development

(i) Please outline the range of services and/or collaborative opportunities to date offered by the CRF to academic, industrial and charity clients. Include details on how the clients access services (diagrams if preferred), how business is generated and the role of CRF staff in delivering the various services. Describe any specialised thematic programmes/ specialised services that will be delivered by the CRF/C; how will you exploit local and national expertise to best effect?

(ii) Please clarify who has overall responsibility for the business development portfolio in the CRF/C.

(iii) Please provide details of funding contracted 1 Jan 2017- 31 Dec 2020 (commercial and non-commercial) in table below. Please state funder, total amount, and amount of award to the CRF. Examples are given below.

The word limit is 300 words.

### 2.6 Scope of supports offered to investigators

- Describe your current customer base and level of demand for particular supports.
- Clearly set out the scope of *supports that will be funded through this award* should this application be successful, and who will deliver them (roles of responsible persons such as Business Development Manager, Quality and Regulatory Affairs Advisor, Biostatistician etc.).
- **Please describe what will change, should this application be successful**\(^\text{19}\); in addition to new supports will some supports no longer be offered? Please show how the team/personnel and infrastructure will be aligned to support the portfolio for the CRF/C.

The word limit is **300 words**.

#### 2.6.1 Please provide a link to the CRF/C published process for access to supports, with assessment criteria, and cut-off dates.

#### 2.7 PPI strategy

PPI should play a critical role in clinical trials. If there is currently no PPI strategy within your CRF/C this is an opportunity to develop an approach to embed PPI within the work of your CRF/C. The HRB together with the Irish Research Council are currently inviting an application for a National PPI Network, with sites across Ireland. Coordination of activities between the National PPI Network and individual CRF/Cs is expected.

Applicants are asked to describe how the CRF/C will support researchers’ PPI activities during the development of an application and during the conduct of a trial. Are other activities foreseen? The word limit is **200 words**.

#### 2.8 Registered clinical trials activity

Please list all **registered** trial activity at the CRF/C from 1 Jan 2017 to 31 Dec 2020\(^\text{20}\) from earliest to most recent, in the Metrics Excel spreadsheet template, available for download from GEMs. A full

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\(^{17}\) Please enter the full value of the award – this may be allocated among a number of centres/collaborators

\(^{18}\) Only capture the value that has been made available to the HRB-CRF, either as direct income or as recouped portion of overheads from the specific award. This should appear in the CRF accounts as income received.

\(^{19}\) Please note that awards are expected to provide support for trial design and planning and basic biostatistics where this capacity does not currently exist.

\(^{20}\) Due to the later submission date of January 2021 for this call, we are asking for registered clinical trial data up to 31 December 2020 to give a better picture of recent activity. We recognise that the data for this year may appear as an outlier due to the impact of Covid-19, however the HRB and the Panel will recognise this.
Please note that only registered trials can be captured in the spreadsheet. If there are multiple registration numbers, please quote the ClinicalTrials.gov registration number.

2.9 Clinical trials: graphical analysis upload

As an overview of the clinical trials portfolio activity please upload a single two-page document comprising 4 graphs of trial data from 1 Jan 2017 to 31 Dec 2020 from the spreadsheet, displaying:

a) All registered trials during period broken down by study phase “Column H" (Please group as follows: I/II/III/IV/Medical Device/Complex Intervention/Not Applicable).

b) All registered trials during period broken down by HRCS “Column L”.

c) # of registered trials commencing recruitment at your site each year during period 2017-2020.

d) Commercial/non-commercial sponsor registered trials commencing recruitment each year during period 2017-2020.

An example of the format of graphs to be used can be downloaded from GEMs for ease of comparability for the reviewers.

2.10 Trial portfolio performance

What metrics do you use to measure performance of individual trials, and of the portfolio overall? What tools/software packages do you use to aid performance monitoring? Please give details of those performance metrics in the period stated 1 Jan 2017 to 31 Dec 2020, in addition to the metrics requested in this section.

Please reference current relevant study metrics for the CRF/C, such as but not limited to: start-up speed\textsuperscript{22}, recruitment reliability\textsuperscript{23}, and note improvements in same over time.

The word limit is \textbf{300 words}.

2.10.1 Please upload your policy on the procedure and criteria for stopping trials.

2.11 Other clinical research activity

Please describe the breadth of research in the CRF/C, and give an indication of the current level of activity in clinical trials, compared with other clinical research studies.

The word limit is \textbf{200 words}.

\textsuperscript{21} The period after all approvals have been obtained and internal CRF green light has been issued

\textsuperscript{22} Start-up speed: median no. of days from receipt of protocol to regulatory approval or ethics approval

\textsuperscript{23} Recruitment reliability: no. of actual subjects randomised as % of no planned per study
2.12 Summary of recent achievements

Please give brief details (bullet points preferred) of recent achievements in the CRF/C and key areas of activity with a brief description of the role of CRF/C staff in each case. Areas to cover may include: key trials attracted to Ireland, healthcare innovations developed/tested, policy and practice influences, education/capacity building, IP and commercial developments, comments from users.

The word limit is 400 words.

Section 3: Business plan 2022-2026

3.1 Work package details

Please add a small number of clearly-described Work Packages which map to the relevant strategic objectives over the term of the HRB investment 2022-2026. Work Packages should have associated tasks, deliverables and milestones.

All CRF/Cs receiving HRB funding will be expected to support, and to contribute to, the national clinical coordination feasibility programme, and resources should be assigned for that purpose. Ideally this should be a distinct Work Package for delineation and ease of reporting. Alternatively, this activity can be captured in one Work Package with all other activities pertaining to coordination with other research infrastructures.

For each Work Package, deliverables will be used to monitor progress by HRB throughout the lifetime of the award if successful, in addition to agreed performance metrics. Task and deliverables should be mapped against estimated completion timelines in a Gantt chart, and any milestones highlighted.

The word limit is 150 words for each Work Package description, and 200 words for the tasks and deliverables.

3.1.1 Optional upload of a PERT chart which shows how the Work Packages link to the Strategic Objectives of the CRF.

3.1.2 You must upload a Gantt chart that lists the above Work Packages, tasks and deliverables against the estimated timelines for completion, together with any additional milestones/key dates (Figure 1).
3.2 Staff resources

Briefly summarise the staffing resources (to be funded by HRB and other resources) required to deliver the Work Packages (include CRF/C Director time requirements), percentage time on the job. Please note the Work Package lead in each case. If you require specialised staff, outline challenges in finding them, and how you will address those challenges. The resource required for the feasibility programme must be specified in terms of the FTE(s) on an associated work package.

Please list new positions that are being requested through the HRB award. Please outline how you are prioritising these positions, and when you expect them to be recruited.

The word limit is 400 words.

3.3 Communication and marketing details

Please provide a brief communications plan to indicate how you plan to identify and engage with your stakeholders and customers (e.g. individual academics/clinicians/allied health professionals, SMEs/multinationals, cooperative groups or clinical trial networks).

Details may include for example:

- Stakeholder analysis
- Key communication messages
- Timing and mode of engagement
- Team member responsible for communications activities

The word limit is 250 words.

3.4 Investment and Financial Model

Please complete the GEMs Budget Template 2022-2026, and in Sections 4.1 give the justification for requested budget and the overall use of resources including co-investment from HI/Hospital/Foundation partners.
Describe the revenue model to recoup costs for the CRF/C. How will this differ for investigator-led and industry studies? Provide details of your approach to secure other sources of income/support for the CRF in the future.

The word limit is **300 words**.

### 3.4.1 Please upload your charging model/list of fees provided for industry studies here.

### 3.5 Key challenges
Please describe anticipated risks during the proposed term of HRB investment and strategies to mitigate their impact.

The word limit is **200 words**.

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**Section 4: Budget**

Please note that the budget requested from HRB must be at least matched by co-investment from the HI/Hospital/Associated charity or Foundation.

- HRB funding will be up to a maximum of €5,000,000 per CRF/C award, inclusive of overheads (30%). The duration of the awards will be up to 60 months. **Funding is not provided for individual trials (definitive interventions or feasibility studies).** Trials and interventions are expected to be funded from other sources, e.g. industry-sponsored, charity funded or through competitive means, such as the HRB DIFA scheme.

- Awards will range between €250k to €1m p.a. over five years.

- Centres with lower levels of trial activity (based on registered clinical trials) will be expected to bid for lesser amounts. Staffing requests should reflect the research capacity within the community it serves.

- The award will predominantly offer support for **operational costs** such as salary for core staff members in the CRF/C. New roles should add clear value to the existing team and address gaps for supporting investigator-led trials, and **must include trial design and biostatistics support where these are currently not available at local level.**

- **An additional budget** per CRF/C should be requested to support **feasibility work** (associated with the national clinical trials coordination programme). Personnel should be appropriate to delivering the feasibility programme and may differ in configuration across the CRF/Cs. The cost of personnel to deliver the feasibility programme is not expected to exceed €70,000 p.a. for all personnel involved, **inclusive of overheads**. These resources must be clearly identified within the budget for the feasibility programme and requested supports justified accordingly.

- **The funding request for each staff position should be clearly justified in terms of added value for the CRF/C.** Each position requested should make sense in terms of the scope of the role, and when it will come on-stream. It is possible that the Panel will recommend funding for some positions but not others.

Funding will be awarded on a claims-made basis. Should the budget allocation for a period not be claimed in full, the balance cannot be carried over and will be lost to the award. Therefore, it is important when developing the budget that applicants plan carefully in order to enable draw-down of the full amount awarded.

Budgets should be broken down using the following budget headings
1. Personnel costs

Must be listed for each salaried personnel under each of the following subheadings (a-c):

Contributions to Personnel costs: as appropriate and justified given the scale and scope of CRF/C activities (e.g. Trial design expertise, Data Lead, PPI Coordinator, Business Development role, QRAM, contributions to Director salary, CRF Operations Manager, Director of Nursing, Administrative support).

| a) Salary | Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with host institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scales for academic researchers [http://www.iua.ie/research-innovation/researcher-salary-scales/](http://www.iua.ie/research-innovation/researcher-salary-scales/)

Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure.

Applicants are advised that public sector pay increases for the period until end of 2020 have been agreed. [https://www.iua.ie/research-innovation/researcher-salary-scales/](https://www.iua.ie/research-innovation/researcher-salary-scales/) For 2022-2026 please apply a salary contingency of 2.5% p.a.

**Applicants should include annual pay increments for staff and related costs (pension contribution, employer’s PRSI contribution, and overhead contribution) in the budget.** |

| b) Employer’s PRSI | Employer’s PRSI contribution is calculated at 11.05% for 2020 |

| c) Employer Pension Contribution | Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution. If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference.

Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs. If requesting
pension costs linked to Circular 6/2007, please provide details as justification for the request.

| 2. Running Costs | Contribution towards costs required to run the CRF/C for example travel, training, legal costs, consultancy fees, licences, IT-related costs etc. training and exchange opportunities to build capacity, PPI costs

Hourly costs of experts can be included here. For more substantive contributions by experts, costs should be allocated to salaries.

Costs associated with involving members of the public or patients in PPI activities e.g. consultation workshops, costs of participation in advisory groups, travel expenses, honoraria, etc. should be charged to running costs.

The following costs are ineligible and will not be funded: inflationary increases, cost of electronic journals.

Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.

| 3. Equipment | Funding for suitably justified equipment can be included in this section. We do not expect costs in excess of €20,000 for this call.

Generic personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e. overhead. Dedicated laptops or similar equipment required specifically for the CRF/C because of the nature of the work, will be considered where appropriately justified. All costs must be inclusive of VAT, where applicable.

| 4. Dissemination Costs | Dissemination and knowledge exchange costs: e.g. outreach events, communication/promotion costs should be captured here, for example costs associated with event/conference attendance, promotional events, production of printed material such as brochures and any other means of communicating with customers and marketing the CRF as detailed in the business plan.

Please refer to the HRB policy on Open Access to Published Research\(^\text{24}\).

| 5. FAIR data Management and Stewardship | Costs related to planning in relation to data management, FAIRification, storage and archiving of research data in line with best practice of data management and stewardship and the FAIR principles, as applicable to a portfolio of studies. Cost of data management support/consultancy calculated by hourly rates should also be included here. Data Steward

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\(^\text{24}\) http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/
consultancy to support CRF/C activities may be included. Please consult Appendix II of the Guidance Notes for examples of eligible costs.

| 6. Overhead Contribution | In accordance with the HRB Policy on Overhead Usage, the HRB will contribute to the indirect costs of the network through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs).

Overheads on the award will be paid directly to the Host Institution. While overheads may be distributed between the HI and Hospital partners by mutual agreement, any portion of the overheads agreed as payable to the Hospital will be routed through the Host Institution.

The following items are included in the overhead contribution: recruitment costs, bench fees, office space, software, contribution to gases, bacteriological media preparation fees, waste fees, bioinformatics access. |

4.1 Budget justification and use of resources

(i) Please give a clear justification for each position requested, including FTE requirements, salary levels etc.\textsuperscript{25} Please set out the proposed role in each case. These HRB co-funded positions should be clearly identified within the requested Organogram in section 5.4.1. Please clarify any change in each case (e.g. change of funding source, increased time for the role with HRB co-investment, new appointment planned).

(ii) Please clarify which person(s) will deliver the feasibility programme, clarify the FTE in each case, and the total cost, including overheads.

(iii) Please describe how the budget requested from the HRB, plus additional co-investment, are sufficient to successfully deliver the Work Packages. Please explain how good use is made of the budget requested, sharing resources where it is appropriate.

The word limit is \textbf{400 words}.  

\textsuperscript{25} Budget as per HRB budget categories
Section 5: CRF/C Team

5.1 Lead Applicant

Details are requested about the Lead Applicant, including their position, and their experience. The Lead Applicant’s contact and CV details (Name, contact information, institution, present position, profession) are managed in the ‘manage my details’ section of GEMS and are automatically included in any application created involving that individual.

5.1.1 Lead Applicant’s Experience and expertise relevant to this application

The Lead Applicant should detail the relevant experience and expertise to support their application. For those with academic positions, they may wish to add a maximum of five most relevant publications, explaining their role in each case. The word limit is 200 words.

5.2 Co-Lead Applicant

HRB expect that the Co-Lead applicant will represent the Hospital or Hospital Group. Where the Lead Applicant represents the Hospital, the Co-Lead may represent the Host Institution, as appropriate. Details are requested about the Co-Lead Applicant including their name, institution, present position, and their experience.

5.2.1 Co-Lead’s Applicant’s Experience and expertise relevant to this application

The Co-Lead Applicant should detail the relevant experience and expertise to support their application. For those with academic positions, they may wish to add a maximum of five most relevant publications, explaining their role in each case. The word limit is 200 words.

5.3 Co-Applicants

The Co-Applicants have a well-defined, critical and substantial role in terms of assisting the Co-Lead Applicants with the leadership and management of the CRF/C. The Deputy Director26 must be included in the list of Co-Applicants. Ideally the Co-Applicant list will include individuals in the CRF/C leading on operations, and the Chairs of the Scientific Advisory Board and/or Public Advisory Board where these exist. It is suggested that an individual in the linked academic institution facilitating the integration between hospital site and university, and enabling sponsorship is included.

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

Registered co-Applicants can then manage/update their contact details (name, institution) in ‘Manage My Details’ and they can decide whether to accept or reject their participation and consent to the application being submitted jointly in their name. If a co-Applicant rejects participation on an application the Lead Applicant is informed and may revise the application accordingly.

Co-Applicants who accept to participate in an application can edit the application. The system will flag through a pop-up warning if another user is working on the application form at the same time. A

26 Or person who will act on behalf of the CRF/C Director in their absence
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. PPI Participants can register in the same way as other Co-Applicants.

5.3.1 Experience and expertise relevant to this application

Each Co-Applicant is asked to provide an overview of their skills and track record relating to their role in the CRF/C. This may include experience and expertise in relation to operations, trial conduct, trial design/planning, biostatistics, commercialisation, business development, influencing healthcare practice and/or policy, Public and Patient Involvement, depending on their role. Reference to recent publications in the field can be added here if relevant to the role, in which case the co-Applicants contribution to each publication should be stated. Co-Applicants can also note contributions to relevant national or international working groups/networks. The word limit for this is 150 words.

5.4 Staff co-ordination, roles and responsibilities

5.4.1 Please upload two organograms as follows (suggest 1 A4 page max each):

Organogram (a) showing the current organisational structure of the CRF/C staff and the reporting lines between different staff level members as of 31 December 2020.

Organogram (b) showing the proposed structure if successful in this call, with any new positions clearly indicated. Please insert names on the chart for ease of identification of senior management.

5.5 Lead Applicant Role (CRF/C Director)

Firstly, please indicate the current commitment to research/clinical/teaching/other, either as a percentage or a proportion of a full time equivalent (FTE). Outline the role of the Lead Applicant (CRF/C Director) in the CRF/C on a day-to-day basis including amount of time to be spent working as Director either as a percentage or proportion of a full time equivalent (FTE).

*These descriptions should clarify the difference in roles and the division of responsibilities between the two Co-Leads.* The word limit is 200 words.

5.6 Co-Lead Applicant Role (Hospital)

Please indicate the current commitment to research/clinical/teaching/other, either as a percentage or a proportion of a full time equivalent (FTE). Outline the role of the Co-Lead Applicant (Hospital) in the CRF/C on a day-to-day basis including amount of time to be spent on work related to the CRF/C either as a percentage or proportion of a full time equivalent (FTE).

*These descriptions should clarify the difference in roles and the division of responsibilities between the two Co-Leads.* The word limit is 200 words.

5.7 Staff co-ordination, roles and responsibilities

(i) Please clarify the scope of the staff roles and responsibilities for Senior Management and Business Leads, *where these are not described within the “Co-Applicant” section*. Briefly describe key skills and track record of staff at senior management level, *where these are not described within the “Co-Applicant” section*.

(ii) Please describe the capacity at senior and middle management level such that the Director is sufficiently supported, and their time is well spent. Describe how staff are managed on a day-to-day
basis to best effect. Describe how resources in the CRF/C are organised to respond to fluctuating demands for support.

(iii) Please identify the team member(s) with responsibility for growing the investigator-led portfolio of trials.

(iv) Please include brief details of training/development provided to staff. This should be bullet points only.

The word limit for this is **250 words**.

**5.8 Staff list upload**

Please upload a word document containing a table with details of current staff. Please state the main source of funding for each staff member, e.g. Host Institution (HI), Hospital (Hos), HRB CRF grant, HRB other, HSE, EU grant, industry, etc. Please state if the staff member is core/short term/long term.

A template word document can be downloaded from GEMs, an example is shown below.

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>FTE</th>
<th>Funding Sources</th>
<th>Core/ Short Term (ST)/ Long Term (LT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director</td>
<td>Jane Smith</td>
<td>1.0</td>
<td>HRB</td>
<td>Core</td>
</tr>
<tr>
<td>Associate Director</td>
<td>Pat Murphy</td>
<td>0.5</td>
<td>HI</td>
<td>Core</td>
</tr>
<tr>
<td>Associate director of nursing</td>
<td>Mary Smith</td>
<td>1.0</td>
<td>HRB</td>
<td>Core</td>
</tr>
<tr>
<td>Senior Research Nurse</td>
<td>John Murphy</td>
<td>0.5</td>
<td>HSE</td>
<td>ST</td>
</tr>
<tr>
<td>Research Nurse</td>
<td>Ann Smith</td>
<td>1.0</td>
<td>HI</td>
<td>Core</td>
</tr>
<tr>
<td>Programme Manager</td>
<td>Jim Murphy</td>
<td>1.0</td>
<td>HI</td>
<td>Core</td>
</tr>
<tr>
<td>Research Manager</td>
<td>Pat Smith</td>
<td>1.0</td>
<td>EU</td>
<td>ST</td>
</tr>
<tr>
<td>Etc</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Section 6: Justification and Added-Value

6.1 Impact statement

The statement should be as specific as possible and provide information that reviewers will find helpful in assessing the potential impact of this five year HRB co-investment in the CRF/C. Describe expected outputs, outcomes and longer-term impacts from this investment in areas such as driving the number of quality of clinical trials in the Irish health system, delivering health innovations, effecting change in health policy and practice, increasing capacity for world-class clinical trials, knowledge generation, economic development and commercial activity in a local/national/international context.

Where impact is mainly anticipated in an Irish context, please describe this for international Panel members.

An implementation plan that outlines the pathway to impact, citing realistic timelines is requested.

The word limit is **400 words**.

6.2 Justification

*Through a co-investment model with the Health Service Executive (HSE), universities and other stakeholders HRB aim to develop a world-class clinical trials infrastructure with the capacity to deliver high-quality clinical trials.*

Please describe how this investment in the CRF/Cs will contribute towards this objective, and specifically (i) improve patient access to high-quality clinical trials and (ii) enhance and expand supports to investigators at a local level, particularly at the earlier stages of trial planning and design, including trial design and statistics support.

Outline why HRB should make this investment in the context of the objectives of this call; clearly set out what is the added-value.

The word limit is **400 words**.

6.3 Co-investment and partner supports

(i) Clearly describe the previous financial support from the HI and Hospital over the period 2017-2020 in scope for this call. This should specify staff and running costs, and exclude capital costs, fit-out/equipment, biobanking support.

(ii) Summarise the level of *proposed HI and Hospital support* for the duration of the proposed investment 2022-2026 (detailed in uploaded Letters of Support in 6.4).

(iii) Show how the proposed HRB investment complements these supports and leverages further investment.

(iv) Clearly demonstrate that HRB funding is not replacing existing financial support from the HI/Hospital/other funding partner.

*We expect the level of co-investment proposed to broadly match/exceed the requested HRB budget in any given calendar year, i.e. where €500,000 HRB budget is requested in Year 2, a similar level combined co-investment by (HI/Hospital/Associated charity) or more is expected in Year 2. Over the five-year period of the award the total confirmed co-investment must equal or exceed the requested HRB budget.*
6.4 Uploads: Letters of Support: Current main funder(s) other than HRB

Formal Letters of Support from the current main funder(s) of the CRF/C must be provided on headed notepaper and signed by the appropriate senior manager (e.g. VP or Dean of the Research in university; CEO or equivalent in Hospital, Hospital Group, associated charity or Foundation). Each Letter of Support must detail the supports provided to date by that organisation, and to be provided during the term, as well as the income to be counted as co-investment. More than one letter may be submitted.

Each letter should provide a narrative description of these supports (e.g. financial management, Technology transfers supports, HR, access to space, cleaning and maintenance).

Further, each Letter of Support must include two budget tables,

- Table (a) detailing the support for the period 1 Jan 2017-31 Dec 2020 (staff and running costs only), and
- Table (b) detailing proposed co-investment for the duration of the award 1 Jan 2022 – 31 Dec 2026 (staff and running costs only).

Please clarify that staff costs and running costs are specific to the work of the CRF/C.

Template budgets can be downloaded from GEMs (and are shown below).

As a minimum, proposed co-investment will need to equal the proposed HRB investment, and demonstrate that support will be maintained, or increased during the term of HRB investment. Sufficient detail must be provided in the budget tables to allow direct comparison of requested HRB budget and the level of financial support to be provided by the co-investment partners.

Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system. It is the responsibility of the Lead Applicants to ensure that applications are completed in full and all necessary documentation is received by the HRB on, or before, the closing dates indicated.
Budget Table A format: support for period 1 Jan 2017-31 Dec 2020, with example shown

<table>
<thead>
<tr>
<th>CRF/C Salary costs supported (includes Employers PRSI and pension contributions)</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position (name)</td>
<td>FTE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QRAM (K.Singh)</td>
<td>0.5</td>
<td>45,000</td>
<td>47,000</td>
<td>49,000</td>
</tr>
<tr>
<td>Director of Nursing (M. Kelly)</td>
<td>1.0</td>
<td>104,000</td>
<td>107,000</td>
<td>111,000</td>
</tr>
<tr>
<td>Administrative assistant (E. Petrova)</td>
<td>1.0</td>
<td>33,000</td>
<td>34,000</td>
<td>35,000</td>
</tr>
</tbody>
</table>

Running costs

| CRF Manager Licence | 20,000 | 20,000 | 20,000 | 20,000 |

Total direct salary and running costs

| 202,000 | 208,000 | 215,000 | 218,000 |

Overhead calculation (30%)

| 60600 | 62400 | 64500 | 65400 |

Total costs supported, including o/h calculation

| 262,600 | 270,400 | 279,500 | 283,400 |
### Budget Table B format: co-investment planned for period 1 Jan 2022-31 Dec 2026

<table>
<thead>
<tr>
<th>CRF/C Salary costs supported (includes Employers PRSI and pension contributions)</th>
<th>€ 2022</th>
<th>€ 2023</th>
<th>€ 2024</th>
<th>€ 2025</th>
<th>€ 2026</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position (name)</td>
<td>FTE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person A (name)</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Running costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Running cost A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Running cost B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Direct Salary and running costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overhead calculation (30%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total costs supported, including o/h calculation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 6.5 Interaction with HRB-funded infrastructures

The investment in Clinical Research Facilities/Centres is expected to mutually reinforce existing HRB investments in clinical trials infrastructure. These clinical trials infrastructures include:

- National Clinical Trials Coordination Programme
- Trials Methodology Research Network,
- Cancer Trials in Ireland Infrastructure, and
- Clinical Trial Networks.

Awardees must undertake to work collaboratively with existing and future infrastructures to collectively improve patient access to clinical trials, and integrate relevant best practices where necessary to support national performance for the benefit of the Irish clinical trials system.

Applicants must describe how they will work with other CRF/Cs in the context of a national network of CRF/Cs. In particular applicants must describe how they will contribute to, and lead as appropriate on National Clinical Trials Coordination Programme Working Groups or programmes of work. CRF/Cs must clearly show how they will support and align with HRB-funded Clinical Trial Networks, including
for cancer, throughout the term of the award. CTNs should be able to access services in CRF/Cs to enable them to design and deliver (externally-funded) trials. Applicants should demonstrate how synergies can be maximised in working with other infrastructures.

Please describe in detail any existing and/or planned ways of working with HRB-funded infrastructures. Clarify any changes proposed.

The word limit is **500 words**.

6.5.1 A one page Letter of Support from all relevant national clinical research infrastructures should be provided, briefly setting out how they will work with the CRF/C for the term of the award.

6.6 International coordination

Applicants should describe how they work with and are coordinated with other relevant international structures (as relevant to their portfolio), such as but not limited to, the UK CRF Network, and ECRIN. What will differentiate this CRF/C? Are shared services envisaged, e.g. with other CRF/Cs?

The word limit is **400 words**.

6.7 Additional upload

You may include one further attachment to support your proposal. A maximum of 5 figures, which can be a combination of images, graphs, tables, as appropriate may be uploaded as a **single document**, which will appear in the Appendix. Figures must not be embedded within the text. The maximum size is 2MB (.doc .docx .pdf).
Submission of Full Applications

The deadline for submission of complete Full Applications will be 13:00 on 19th January 2021

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.

It is the responsibility of the Co-Lead Applicants to upload all supporting documentation to GEMS prior to submission. If the documentation is not received by the HRB on time, in the correct format or is not properly signed or submitted, the application may be deemed ineligible without further review.

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

The HRB’s procedure for appealing funding decisions is available at http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/
Appendix II: FAIR Data Management

Introduction

For researchers, the move to FAIR and open\textsuperscript{27} data, where possible, means that they have the responsibility to think about what data their research will produce, how these data will be described, and how they can be made available in such a way so as to benefit science and society in general. This means that they have to draw up a data management plan (in collaboration with professionally trained colleagues) and find suitable data repositories at a very early stage of their research. FAIR principles should be applied to all research involving data and/or software creation and so be included in all data management plans (DMPs). The DMP is not be a goal in itself and should not be regarded as an additional administrative hurdle. It should instead provide an opportunity at an early stage of the research project to consider how the data generated within a project will be stored, managed and safeguarded, and thus be part of the research process from the outset. As a project progresses, the data generated may well change in type and volume, so the DMP should be seen as a dynamic framework which should be maintained and modified as the research advances.

DMP Requirements

The HRB’s policy on management and sharing of research data\textsuperscript{28} came into effect on 1st January 2020. In line with this policy, all \textbf{successful applicants will be required to submit a completed data management plan (DMP) to the HRB at the beginning of the study and a final updated version of the DMP with the final report at the end of the study.} The DMP will need to be submitted alongside a certification of approval from the designated representative(s) within the Host Institution. Successful applicants will be expected to use the HRB Data Management Plan template available through DMPOnline - \url{https://dmponline.dcc.ac.uk/}

The requirements of the HRB’s DMP template can be found here \url{https://dmponline.dcc.ac.uk/template_export/1814665590.pdf}

\textsuperscript{27} Please note that not all FAIR data are necessarily open. Where data raises data protection or security concerns, controls and limits on data access will be required. In some cases, it will be appropriate for researchers to delay or limit access to data in order to secure intellectual property protection. Any such restrictions on access should be justified, made explicit via machine-actionable licensing and built-in accessibility protocols mechanisms.

\textsuperscript{28} \url{https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-management-and-sharing-of-research-data/}
FAIR Data Management Costs

Examples of FAIR Data Management Costs are listed in the table below. Costs related to management, FAIRification, storage and archiving of research data (as part of the DMP pilot the HRB is currently conducting) in line with best practice of data management and stewardship and the FAIR principles. Some of the eligible costs may include:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>People</td>
<td>Staff time per hour for data collection, data anonymisation,</td>
</tr>
<tr>
<td></td>
<td>staff time per hour for data management/stewardship support, training, etc</td>
</tr>
<tr>
<td>Storage and computation</td>
<td>cloud storage, domain hosting charge</td>
</tr>
<tr>
<td>Data access</td>
<td>secondary data access, costs for preparing data for sharing (eg anonymisation)</td>
</tr>
<tr>
<td>Deposition and reuse</td>
<td>costs for depositing research data and metadata in an open access data repository</td>
</tr>
<tr>
<td></td>
<td>e.g. defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing</td>
</tr>
<tr>
<td>Others</td>
<td>Please further explain</td>
</tr>
</tbody>
</table>

Please note this list is not exhaustive and aims to provide examples only of eligible costs. Please note the HRB is currently not covering the cost of long-term preservation of data.

Who can help?

Support for developing Data Management Plans may be available at Host Institution level from the following people:

Jacintha Maron, Cork Institute of Technology
Aoife Geraghty, University of Limerick
Caleb Derven, University of Limerick
Aishling Hayes, University of Limerick
Trish Finnan, National University of Ireland Galway
Peter Corrigan, National University of Ireland Galway
Stephen Madden, Royal College of Surgeon Ireland
Andrew Simpson, Royal College of Surgeon Ireland
Brendan Palmer, University College Cork
Eoghan O’Carraghin, University College Cork
Aoife Coffey, University College Cork
Appendix III: References/Useful Links

Study design for interventions

  http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0150205

- “The PRECIS-2 tool: designing trials that are fit for purpose” by Louden et al.  
  http://dx.doi.org/10.1136/bmj.h2147

- “A process for Decision-making after Pilot and feasibility Trials (ADePT): development following a feasibility study of a complex intervention for pelvic organ prolapse” by Bugge C et al.  

- “Developing and Evaluating Complex Interventions” by MRC, UK  
  www.mrc.ac.uk/complexinterventionsguidance

- “Process evaluation of complex interventions: Medical Research Council guidance” by Moore GF. et al.  
  http://dx.doi.org/10.1136/bmj.h1258

- “Using natural experiments to evaluate population health interventions: Guidance for producers and users of research evidence” by MRC, UK  
  www.mrc.ac.uk/naturalexperimentsguidance

- COMET (Core Outcome Measures in Effectiveness Trials) Initiative: development and application of agreed standardised sets of outcomes, known as ‘core outcome sets’  
  http://www.comet-initiative.org/
Study registration

- **International Clinical Trials Registration Platform** (run by the WHO)
  [http://apps.who.int/trialsearch/Default.aspx](http://apps.who.int/trialsearch/Default.aspx)

- **European Clinical Trials Database** (EudraCT): database of all regulated clinical trials which commenced in the EU from 1 May 2004

- **US National Library of Medicine database**: database of privately and publicly funded clinical studies – regulated and unregulated - conducted around the world
  [https://www.clinicaltrials.gov/](https://www.clinicaltrials.gov/)

Reporting

- **Consort 2010 Statement**: updated guidelines for reporting parallel group randomised trials
  [www.consort-statement.org](http://www.consort-statement.org)

- **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
  [https://www.equator-network.org/library/](https://www.equator-network.org/library/)

- **Registry of Research Data Repositories**
  [http://www.re3data.org/](http://www.re3data.org/)

- **Zenodo Data Repository (OpenAIR)**
  [https://zenodo.org/about](https://zenodo.org/about)

Public and Patient Involvement

- **Public Involvement Impact Assessment Framework**: Provides tools for successful involvement of members of the public in research projects and for assessment of impacts
  [http://piiaf.org.uk/](http://piiaf.org.uk/)

- **PPI cost calculator**

- **European Patient Forum Value + Handbook**: For Project Co-ordinators, Leaders and Promoters On Meaningful Patient Involvement
• **The James Lind Alliance Priority Setting Partnerships:** Research priorities in disease areas set jointly by patients, clinicians and researchers
  
  [http://www.jla.nihr.ac.uk/](http://www.jla.nihr.ac.uk/)

• **INVOlVE UK website for resources on Public and Patient Involvement in research**
  
  [http://www.invo.org.uk](http://www.invo.org.uk)

• **How to involve people in research**
  

Data management and sharing and FAIR principles

• **Digital Curation Centre:** How to develop a data management and sharing plan and examples DMPs
  

• **FAIR data principles FORCE 11**
  
  [https://www.force11.org/fairprinciples](https://www.force11.org/fairprinciples)

• **UK Concordat on Open Research Data (July 2016)**
  

• **Guidelines on FAIR data management plans in Horizon 2020**
  

• **FAIR at the Dutch centre for Life sciences**
  
  [https://www.dtls.nl/fair-data/](https://www.dtls.nl/fair-data/)

• **Registry of Research Data Repositories**
  
  [http://www.re3data.org/](http://www.re3data.org/)
Gender issues in research

- **Examples of case studies in Health & Medicine where gender/sex in research matters**

- **Gender Toolkit in EU-funded research for examples and guidance**

Evidence synthesis

- **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](http://www.thecochranelibrary.com)

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

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