Investigator-led Clinical Trials Programme (ILCT) 2025

Definitive Interventions and Feasibility Study Streams

Definitive Intervention Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	05 February 2025
Submission deadline 1	25 April 2025 @13:00
Submission deadline 2	18 July 2025 @13:00
Submission deadline 3	17 October 2025 @13:00

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie), and this system will close automatically at the stated deadline and timeline listed above.

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

The HRB expects applicants to engage with their Host Institution to facilitate a review of the application, including any institutional sponsor risk assessment. This is in particular to enable review of the application for detailed costings, and any approval of a sponsorship role. Please liaise with your Host Institution to ensure you are fully aware of institutional requirements.

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1 Introduction

The Health Research Board (HRB) Strategy 2021-2025[1] sets out a lead role of the HRB to invest in research that delivers value for health, the health system, society, and the economy. Objective 1.2 of the strategy aims to "Invest in clinical trials and interventions studies to drive excellence and innovation and to deliver benefits for patients, the health system, and the economy".

The HRB has supported clinical trials through the Definitive Interventions and Feasibility Awards (DIFA) scheme. Following a process of strategic stakeholder engagement, the HRB has recognised the need to revise the DIFA scheme, to ensure it continues to meet the requirements of the research community, patients and with wider healthcare system. HRB has therefore revised the DIFA scheme to provide a more flexible approach to proposal submission and to ensure a more timely response for funding decisions.

Reflecting the overall revisions to the scheme, HRB has renamed the scheme **"Investigator-led Clinical Trials (ILCT) Programm**e" to better reflect its purpose to support investigator-led clinical trials.

The Investigator-led Clinical Trials (ILCT) Programme retains the scope, aims and objectives of DIFA, and will continue to support both definitive intervention and feasibility studies.

1.1 Changes from previous rounds of DIFA

The following changes are included in the Investigator-Led Clinical Trials (ILCT) Programme scheme:

- ILCT will run two separate application streams: one for definitive intervention studies (DIs) and one for Feasibility studies (FS).
- The application process for both the DI and FS streams is a one stage process. This will speed-up the timeline for assessment, leading to quicker funding decisions.
- The call is now structured as an open rolling call, where applications can be submitted at any time up until October 2025. Within the overall call, there are three cycles of assessment linked to pre-agreed application submission deadlines, after which the assessment process (peer, public and panel review) will take place. This provides increased opportunities to apply for funding for clinical trials during the lifetime of the call.
- It is anticipated that there will be 3 funding decisions throughout 2025 and 2026 (November 2025, February 2026, May 2026) aligned to HRB Board meeting approval dates. See Section 10 for detailed information on timelines and steps within the assessment process.
- The aims and objectives, and scope of the call remain unchanged.
- The co-lead applicant option is removed from the ILCT programme. The aim of this was to provide opportunities for health and care practitioner investigators who do not have the required academic track record to apply as Lead Applicant. Experience with previous schemes has shown that this has not achieved its intended aim. Investigators who do not

[1] https://www.hrb.ie/strategy-2025/

have the required academic track record to apply as the Lead Investigators can still apply to the ILTC Programme scheme as a Co-Applicant.

- The HRB strongly recommend the inclusion of a biostatistician as a Co-Applicant on the application
- The maximum available budget for Definitive Intervention studies has increased to €1,300,00 (including overheads), and for Feasibility Studies to €430,000 (including overheads). This reflects the general increase in research related costs including salaries and align funding for feasibility studies with other HRB-funded project grants.
- Broadening the types of trial methodology sub-study embedded within the trial proposal. The sub-study may take the form of a Study Within A Trial (SWAT), or other approach focused on improving the design, conduct, analysis, reporting, or dissemination of trials in areas where there is current uncertainty.

2 Aim and Objectives

The overarching **aim** of the ILCT programme is to achieve tangible benefits to patients, peoples' health and health services through **support of studies:**

- **evaluating the effectiveness of a definitive trial of an intervention**. The evaluation may be of any appropriate design and will provide high quality evidence on the efficacy and/or effectiveness, cost and broad impact of the intervention (Definitive Intervention stream)
- stand-alone **feasibility studies conducted in preparation for a future definitive trial of an intervention** are also supported to achieve a pipeline of definitive intervention studies (Feasibility stream)
- **Trial methodology sub-study (including SWATs)** [2] built into the main or feasibility study to explore primary trial methodology questions. This sub-study may take the form of a Study Within A Trial (SWAT) or other approach focused on improving the design, conduct, analysis, reporting, or dissemination of trials in areas where there is current uncertainty.

The **objectives** of the ILCT Programme are to:

- Fund research teams to conduct high quality definitive trials of interventions ("definitive interventions"), and feasibility studies in clinical and/or population health research and/or health services research that are relevant to health priorities internationally and/or nationally
- Support research that translates research knowledge into new ways of treating patients, delivering care or changing behaviour
- Support conduct of trial methodology research within the context of proposed trials or feasibility studies
- Improve health outcomes and health service delivery

[2] SWAT Resources developed by the Trial Forge SWAT Network: https://www.york.ac.uk/healthsciences/research/trials/swats/swatresources/

3 Scope of Call

The ILCT Programme supports research that addresses questions of direct relevance to the improvement of patient care, health of the public and health services and that has strong potential to have immediate use for decision makers in everyday clinical practice or policy.

The types of studies funded via the two streams are:

1. **Definitive intervention studies** of any appropriate design, including randomised controlled trials and non-randomized trials, designed to assess the effectiveness, cost and broad impact of an intervention.
2. **Stand-alone Feasibility studies** conducted in preparation for a future definitive intervention study. A feasibility study is designed to test the acceptability of the intervention, including by study participants, to determine the response rate and the attrition rate in recruitment and calculating the sample size. In addition, the barriers to the intervention from the perspective of participants can also be identified.[3] The sole aim of funding feasibility studies is to establish a pipeline for definitive intervention study, therefore clear progression criteria to a substantive study are required. The applicant should indicate the proposed research question of the future substantive study. It is not possible to apply for a feasibility study, including a pilot study, and the associated definitive trial of the intervention at the same time.
3. **Methodology sub-study (including SWATs)** [4] built into the definitive intervention or feasibility study to explore **primary trial methodology questions**. To encourage and support further methodology sub-studies within the HRB-funded portfolio additional funding of up to €20,000 (inclusive of overheads), will be available towards identified costs of conducting a methodology sub-study. The trial methodology sub-study should be conducted to the same high standard as the main trial (e.g., having a written protocol and plan for dissemination).

Prior to considering funding for a definitive intervention trial, the review panel will request the results of feasibility work (with a discussion around acceptability, recruitment, compliance issues, delivery of the intervention, settings, recruitment and retention, effect size etc. as appropriate)

No preference is given for any particular type of intervention. The term **intervention** includes any method used to promote health, prevent and treat disease and improve health care delivery. Examples include:

- Pharmaceuticals (Investigational Medicinal Products)
- Procedures such as physiotherapy, surgical, radiation, speech and language therapy and others
- Medical devices
- Diagnostic tests
- Screening programmes
- Behavioural or psychological

[3] Shahsavari H, Matourypour P, Ghiyasvandian S, Nejad MRG. Medical Research Council framework for development and evaluation of complex interventions: A comprehensive guidance. J Educ Health Promot. 2020 Apr 28;9:88. doi: 10.4103/jehp.jehp_649_19. PMID: 32509896; PMCID: PMC7271909.

[4] SWAT Resources developed by the Trial Forge SWAT Network: https://www.york.ac.uk/healthsciences/research/trials/swats/swatresources/

- Educational
- Settings of care
- eHealth
- Other studies not listed above

We expect that evidence is provided to support the case for specific interventions, and this evidence has been gathered systematically, i.e. as systematic reviews or other evidence synthesis formats, or via other published trial data. Simple literature overviews are not sufficient. Evidence synthesised systematically to include evidence of (1) a systematic identification of previous work, (2) critical appraisal, (3) synthesis of the evidence and (4) interpretation of findings.

Cancer specific studies

Aligned to HRB's investments in cancer clinical trials infrastructure, €3M of the total ILCT Programme budget is aimed at supporting cancer-specific trials (both definitive intervention and or feasibility studies) quality permitting within the overall call. The application, assessment process and criteria will be the same for all applications.

International studies

Participation in **international studies** at feasibility stage and participation in full-scale international studies subject to evidence of feasibility within Irish sites is permitted. This may be the case where Ireland may be a recruitment site in an investigator-led trial, or alternatively where the team in Ireland is playing a leadership role in a potentially high-impact study. **Where the team in Ireland is not playing a key role in an individual trial, the applicants must clearly articulate the value for Ireland.** This may be, for example, gaining experience in delivering complex studies, establishing a collaboration for future studies, or enabling patient populations in Ireland to participate in trials which otherwise they could not access (e.g. in rare diseases).

Applicants will be asked to provide details on the status, funding source, recruitment targets and outline the role of the Irish applicant as lead of the study or as participants. **Applicants as part of ongoing international trials will be required to provide a copy of the trial protocol.** If the study is live, a letter from the Chair of the Independent Data Monitoring Committee (IDMC) outlining how the recruitment is progressing and any issues that may be relevant for reviewers should be provided. This will assist the reviewers and panel members in reviewing aspects of commitment and access and overall study feasibility.

Costs associated with trial activities outside the island of Ireland are not eligible costs for the ILCT Programme. However, exceptions may be made in the case of rare disease trials (where overall participant numbers may be low), or where per patient costs of participants from Low to Middle Income Countries are included. In addition, where Ireland is leading an international trial, costs relating to sponsorship/trial coordination can be included.

All Trials Campaign

The HRB is a signatory of the All Trials campaign (http://www.alltrials.net/) and supports the aim of having all trials registered and all results reported. HRB extend this ambition to all HRB-funded intervention studies. Unregistered and unreported intervention studies are unethical and cause harm

because 1) the work may be repeated, 2) a metanalysis of published results will be skewed, potentially leading to flawed clinical decisions and 3) participants have a legitimate expectation that results will be published. HRB therefore requires all HRB-funded studies to be registered in a publicly accessible register prior to initiation of the study. 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 study will be submitted for publication.

3.1 Out of scope

The ILCT Programme will not fund[5]:

- **studies involving the development of an intervention.** While a feasibility study, submitted through the feasibility stream, may be useful for identifying further optimisation of an intervention, for a definitive intervention study it is expected that the intervention has been fully developed
- Observational studies not involving an intervention
- Research involving animals
- Pre-clinical studies
- PhD Research
- Stand-alone systematic reviews
- Translational Research. Costs for sample collection and biobanking in the context of the intervention are allowed where justified, however costs for the analysis of samples are not
- Applications seeking to evaluate all phases of an intervention. Applicants must apply for feasibility studies separate to the associated full scale, definitive trial. Applications for stand-alone feasibility studies should be submitted via the Feasibility study stream
- Applications which are solely or predominately health service developments or implementation of an intervention without a predominant research element. The HRB will not fund the cost of providing the service or intervention itself, only the research element
- Applications for research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer
- Applications from individuals applying for, holding, or employed under funding received from the tobacco industry [6]
- Applications from individuals applying for, holding, or employed under funding received from the alcohol industry and related actors[7]

[5] https://www.hrb.ie/wp-content/uploads/2024/05/HRB-Position-Statement-on-Tobacco-and-Alcohol-industry-funding-1.pdf

[6] Any company, entity, or organisation involved in the development, production, promotion, marketing, or sale of tobacco in any country of the world. The term also includes any companies that are a subsidiary or a holding company or affiliate of the above. This also includes e-cigarette companies and non-tobacco related companies which are fully or partially owned by the tobacco industry

[7] Including social aspects/public relations organisations (SAPROs) funded by alcohol companies or trade associations in which such companies are members.

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

4 Funding Available, Duration and Start Date

Over 2025 and 2026, HRB plans to commit in the region of €12M to the ILCT Programme, including €3M aimed at supporting cancer trials. Quality permitting it is expected that a minimum of 10 awards will be funded through the programme.

The ILCT Programme will provide funding for Definitive Intervention studies up to a maximum of **€1,300,000** (inclusive of overheads) (or €1,000,000 exclusive of overheads) per award, for up to 60 months duration.

Funding for Feasibility Studies will typically be in the region of **€430,000** (inclusive of overheads) (or €320,000 exclusive of overheads) or below, with durations of between 12-36 months.

The HRB acknowledges that feasibility studies for complex interventions may incur higher costs than feasibility studies for RCTs. The cap of €430,000 for feasibility studies may be exceeded in exceptional cases where suitably justified.

The grant will provide support for research-related costs including salary for research personnel, running costs, PPI costs, Sponsor costs, data management and dissemination costs, and overheads contributions.

An additional €20,000 (inclusive of overheads) can be requested for conducting a **trial methodology sub-study** in addition to the overall budget.

The budget requested and award duration of all proposals must reflect the scale and nature of the proposed research. Reviewers will thoroughly assess this when reviewing the proposal and will pay particular attention to feasibility studies in this respect. The maximum funding envelope available is **not** an invitation to apply for the maximum amount.

Applicants should seek guidance on the budget at an early stage from their Host Institution or relevant Infrastructures to ensure the study is costed appropriately.

Please refer to the HRB Clinical Trials and Interventions Research Governance Policy[8] for further details. Please note that **all trials** (Regulated and non-Regulated) directly funded by HRB will require a sponsor. HRB cannot act as the sponsor. The sponsor for HRB-funded trials cannot be an individual or company.

The earliest start date of the Grant is 01 February 2026 for applications submitted before 25 April 2025. Please see the review process section (Section 9) for additional detail.

5 Eligibility Criteria

[8] https://www.hrb.ie/wp-content/uploads/2024/05/HRB-Clinical-Trials-and-Interventions-Governance-Policy- /

This call is open to Host Institutions (HI) from Republic of Ireland. Applicants from HIs in Northern Ireland cannot apply as Lead Applicant, but they can apply as a Co-Applicant/Collaborator and receive funding (if fully justified).

5.1 Applicant Team

Applicants must demonstrate that the research team contains the necessary breadth and depth of expertise in all the methodological areas required to deliver the proposed study. Appropriate multi and inter disciplinary involvement in the research team is essential. As appropriate to the proposed study, experts in trial methodology, statistics, trial management, health economics, PPI contributors, health service research, behavioural science, qualitative research methodologies, psychology, sociology etc. should be included as Co-Applicants or as official Collaborators or requested as funded personnel. **The HRB strongly recommends including a biostatistician with an appropriate FTE as a Co-Applicant.** Biostatisticians should be involved in all stages of the grant, from design and analysis of the trial, to reporting of results.

Roles and responsibilities of funded personnel must be differentiated and clear. Reviewers will thoroughly assess the level of experience matched with the supervisory and up-skilling arrangements proposed in scoring the application.

Unlike the HRB's career development awards, this scheme is not framed as a training initiative and is **not suitable for students in pursuit of a higher degree.** The Applicant Team has been made more flexible to allow for a broader mix of Co-Applicants and Collaborators, in recognition of the growing size of the team necessary to deliver the study successfully. For studies that require substantial coordination, applicants should strongly consider the appointment of a study manager or coordinator (for small studies this may be one of your Co-Applicants rather than a dedicated post).

The HRB expects that applicants will collaborate, where appropriate, with partner organisations such as hospitals, health agencies, universities, local government, voluntary organisations and/or industry. The HRB encourages applicants to secure co-funding, where possible, from partner organisations. Applicants must also demonstrate the commitment of their partner organisations with evidence of existing partnerships and/or plans on how they will contribute to this award.

Co-applicants and Collaborators from the island of Ireland and/or outside the Republic of Ireland are welcome where their participation clearly adds value to the project.

5.1.1 Lead Applicant

The **Lead Applicant** will serve as the primary point of contact for the HRB during the review process and on the award, if successful. The Lead Applicant will be responsible for the scientific and technical direction of the research programme. They have primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of the HRB.

The Lead Applicant **must**:

- 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 an individual who will be recognised by the Host Institution upon receipt of an award 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. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

They **must** show evidence of achievement as an independent researcher in their chosen research field by:

a) Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs (e.g., published book chapters, reports to government, research data and datasets, research materials, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence on health policy and practice, outreach and/or knowledge translation activities, media coverage or other relevant activities) and/or any other relevant outputs that have resulted in a significant impact in their field.

b) Demonstrating record of independence by showing that they have secured at least one peer-reviewed research grant for a research project/s, as either the Lead Applicant or a Co-Applicant. Funding received for travel to seminars/conferences and/or small personal bursaries will not be considered in this regard.

c) Show evidence that they possess the capability and authority to manage and supervise the research team.

d) Demonstrate relevant experience and expertise in leading and conducting clinical trials and other intervention studies.

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

As signatory of the DORA Declaration[9], the HRB is committed to supporting a research environment where importance is placed on the intrinsic value and relevance of research and its potential impact in society (HRB – Declaration on Research Assessment).

5.1.2 Co-Applicants & Collaborators

The number of individual Co-Applicants and Collaborators within the Research Team is not prescribed however, **the total number of Co-Applicants and Collaborators must not exceed 15.**

Co-Applicants

A Co-Applicant has a well-defined, critical, and substantial role in the conduct and steering of the proposed research. Co-Applicants may receive funding for items such as running costs and personnel but will not receive support towards their own salary if they are in salaried positions. However, researchers in contract positions/independent investigators, knowledge user and PPI contributor Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to

[9] https://sfdora.org/

the research for the duration of the award. HRB would not anticipate more than 10 **Co-Applicants** to be included (up to a **maximum of 15 Co-Applicants and Collaborators in total**).

Each Co-Applicant must confirm their participation and is invited to view the application form online. The terms of any co-application should be determined early, and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up co-application agreements.

Collaborators

A Collaborator is an individual or an organisation who will have an integral and discrete role in the proposed research and is eligible to request funding from the award when properly justified. Named collaborators may include investigators or organisations from outside the Republic of Ireland, but an individual or organisation should **only** be named as Collaborator if they are providing specific contributions (either direct or indirect) to the activities. A collaborator may provide training, supply samples or kits, provide access to specific equipment, specialist staff time, staff placements, access to data and/or patients, instruments or protocols, industry know-how, or may act in an advisory capacity. Collaborators can come from a range of backgrounds such as academia, the private sector, a healthcare organisation, the charity sector, or a patient group.

Profile details **must** be provided for ALL collaborators. In addition, each collaborator **must** complete a **Collaboration Agreement Form**. A template Collaborator Agreement form will be made available on GEMS for download. We would not anticipate more than **10 Collaborators** to be included (up to a **maximum of 15 Co-applicants and Collaborators in total**).

If access to samples, vulnerable population groups, healthy volunteers or patients, data, databases, or a link to an existing national or international study (e.g., an existing cohort or longitudinal study) are an integral part of the proposed project, evidence of commitment and access must be demonstrated by having the Data Controller or key Gatekeeper of a study included as a Collaborator.

The applicant team will be asked to describe any relevant agreements that they have entered into to facilitate their partnership working. The terms of any collaboration should be determined early, and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, ownership and copyright, access and sharing of data and samples etc. when working up Partnership proposals.

5.1.3 Funded Personnel

Applicants must demonstrate that the level, expertise, and experience of proposed research personnel matches the ambition and scale of the project and that they possess the necessary breadth and skills in all methodological areas required to deliver the proposed programme of work. Alignment between personnel requested and the proposed project should be demonstrated. Roles and responsibilities of funded personnel must be differentiated and clear.

6 Host Institution

A HRB Host Institution is a research-performing organisation approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all HRB award schemes. The **Host Institution for the award** is normally that of the **Lead Applicant** but it may be another organisation/institution designated by the research team, where it is clearly justified. In order to be eligible to apply for funding, an Institution must be an **approved** HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for research performing organisations to be approved as HRB Host Institutions can be found on the HRB website[10].

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

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

Note: Applicants are encouraged to engage with their Host Institution to avail of any infrastructures, specialised or other supports/advice available to them internally. This specifically includes requirements for any institutional risk assessment and approval of a sponsorship role.

7 Access and Support from Clinical Research Infrastructures

Applications are expected to avail of the advice, research design including PPI, data management services and other forms of support for the delivery of the study from existing research infrastructures such as a Clinical Research Facility/Centre (CRF/C), the HRB Trials Methodology Research Network (HRB TMRN)[11], thematic Clinical Trials Networks (CTNs) or Cancer trials in Ireland Groups and Cancer trials network.

Where applicants are availing of such services, they are required to provide additional information detailing the scope and nature of the engagement (this includes national and international facilities, Units and Networks as required).

[10] https://www.hrb.ie/wp-content/uploads/2024/05/HRB-Policy-on-Approval-of-Host-Institutions.pdf

[11] Support by the HRB-TMRN requires the inclusion of a primary methodological sub-study within a trial (e.g. SWAT) or must include a non-standard novel trial design

Infrastructure Agreement Form

An **Infrastructure Agreement** form will be requested as part of the application addressing the nature/scope of the service or collaboration, the rationale behind the choice of facility/centre/network and any costs associated with the project (including those provided as in-kind contributions). **Applications proposing research with patients which do not detail advice and/or support from a CRF/C, CTU will be asked to justify why they have not done so.**

In line with the HRB Clinical Trials and Interventions Research Governance Policy, [12]regulated clinical trials such as a clinical trial of an investigational medicinal product or a clinical investigation must be conducted under the governance of a Clinical Research Facility/Clinical Research Centre (CRF/C). Evidence of this must be provided to HRB in the form of a completed Infrastructure Agreement Form, setting out governance arrangements, signed by the Director of the facility.

8 Application, Review Process and Assessment Criteria

8.1 Grant E-Management System (GEMS)

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie/). Applications can be submitted at any time from when the call opens.

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

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

8.2 Application submission

Please note the change in the application submission and review process for the ILCT Programme. The application process is now a one-stage process, so there is no longer a pre-application and shortlisting stage. The ILCT Programme will open on GEMs from February 2025, with three application submission dates (April, July and October 2025) and three associated funding decisions between 2025 and 2026 (anticipated in November 2025, February 2026, May 2026).

8.2.1 Resubmissions

Unfunded proposals previously submitted to HRB DIFA or to earlier cycles of the ILTC 2025 Programme may be resubmitted one additional time to the ILTC call (i.e. two submissions in total). In

[12] https://www.hrb.ie/wp-content/uploads/2024/05/HRB-Clinical-Trials-and-Interventions-Governance-Policy-1.pdf

these cases, applicants must state that the application relates to a previously application and identify the relevant HRB scheme.

Resubmissions must clearly demonstrate that the reviewer comments from the previous initial application submission have been considered in the development of the new application. Where reviewer's comments have not been addressed, applicants should clearly explain why.

A resubmission statement will be required, identifying how the application is different to that previously submitted, and if applicable, how the applicants have addressed previous reviewer's comments. The resubmission statement will be required to be submitted via GEMS, along with the new application.

HRB will treat the revised application as a new proposal.

Applications will only be permitted to be resubmitted to ILCT 2025 once.

8.3 Review Process

The Review process is the same for both DI and FS streams. Applications will be initially checked for eligibility by HRB staff members. Following the initial eligibility check, each eligible application submitted to the ILCT Programme will undergo a two-phase review process.

Phase 1 – International Peer Review and Public Review

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

International peer 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. Peer reviewers will focus on the stated assessment criteria for the call and will provide comments as well as a score which is visible to the HRB and to panel members.

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

Public Reviewers are asked to comment on the following:

- The plain English summary (Lay Summary)
- PPI in development of and throughout the project
- Making it straightforward for research participants

The HRB will share the public review feedback with the PPI Ignite Network team in the Host Institution where applicable.

Applications may be shortlisted for considerations by the Panel using the average of the peer review scores.

Applicant Response

Applicant teams will be provided with a time-limited opportunity to respond to peer and public review comments (see Section 10 Timeframe). Neither peer nor public review comments will include any reference to the reviewer's identity. Public review ratings will be shared.

Once notified that the application is short-listed the peer review and public review comments will be made available to the Lead Applicant on their GEMS personal page. The Lead Applicant will have up to 10 working days only to submit their response through GEMS, and the response has a **maximum word count of 2000 words only for the peer review response** (including references) and **500 words only for the public review response**. No figures can be uploaded. The response will be provided to members of the Review Panel, in advance of the Panel meeting, along with the application, the peer and public review comments and rating. The response to the public review will be given to the public reviewer as a feedback and learning opportunity.

Phase 2 – International Panel Review

HRB established an international Standing Panel (comprising an independent Chair and 10-12 international panel members) for the DIFA scheme in 2020 to provide continuity of review between DIFA calls. The Standing Panel have participated in the previous DIFA calls in 2020 and 2023 and will be continued for the ILTC 2025 call.

Panel members have access to the application, peer and public reviews and the applicants' response. HRB staff members are present at the meeting to clarify any procedural aspects for the Chair or Panel members and to take notes for the feedback process.

The panel will review the strengths and weaknesses of the application relating to the assessment criteria detailed below. Successful applicants are expected to score well in all review criteria. While PPI is not a stand-alone assessment criterion, it may influence scores under any criterion as relevant to the application.

At the end of the panel meeting, a final score is collectively agreed for each application and applications will be ranked according to score.

Gender balance of the Lead Applicant will be considered where required to prioritise proposals with the same scores in the Panel ranking list.

The recommendations of the Review Panel will be presented for approval at the next scheduled HRB Board meeting. When the Board of the HRB has approved the process and recommendations, HRB staff will contact the Lead Applicants and Host Institutions to notify them of the outcome. A summary of Panel Member's comments and the panel discussion comments will be issued to the Lead Applicant following the Board approval stage.

8.4 Assessment Criteria

The following assessment criteria, which have equal weight, will be used to assess applications to the ILCT Programme **by peer-reviewers and the panel reviewers**. Successful applications will be expected to **rate highly in all criteria**.

1. **Case for the study**
    - Important research question

- Evidence supports the need for this study

2. **Potential for impact of the study**
    - Likely to impact on patients, public and/or healthcare system
3. **Research team and environment**
    - Appropriate skill mix and experience
    - Appropriate supports, infrastructures and research environment
4. **Appropriate methodology**
    - Study design and methodology will answer the research question
5. **Feasibility of the study**
    - Study will be delivered to time and on target
    - Resources are sufficient and reasonable

Panel members will be advised to take PPI approaches into consideration under any of the assessment criteria if considered relevant.

9 Timeframe

Stage	Cycle 1	Cycle 2	Cycle 3
Call Opening	**February 2025**		
Submission deadline	25 April 2025	18 July 2025	17 October 2025
Scientific peer and Public review	February - July 2025	July - October 2025	October - January 2026
Applicant response	July 2025	October 2025	January 2026
Panel review meetings	September 2025	December 2025	March 2026
Panel recommendations presented to HRB Board	November 2025	February 2026	May 2026
Contracting stage (subject to approval)	November 2025	February 2026	May 2026
Earliest start date	**01 February 2026**	**01 May 2026**	**01 August 2026**

10 Contacts

For further information on the ILCT Programme contact:

Karen Crowley
Project Officer
Research Strategy and Funding
Health Research Board
E. ILCT@hrb.ie

Fiona Manning
Programme Manager
Research Strategy and Funding
Health Research Board

The HRB reserves the right to reject any application that does not meet the terms of this call. **The HRB's Policy on Appeals on funding decisions is available at** https://www.hrb.ie/wp-content/uploads/2024/09/HRB-Policy-on-Appeals-2.pdf.

Appendix I: Guidance on the Application Form for the Definitive Intervention stream

Please review carefully as changes have been made from the previous round of this call (DIFA).

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**[13], available on the left-hand column of your GEMS profile homepage, for further information.*

The **Lead Applicant** must create the application, but it can then be jointly completed with named co-applicants.

Lead Applicants can register on GEMS, and they will receive an email to confirm their registration and log in details. The Lead 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.

The Applicant will be asked to complete a check list of mandatory questions. In order to access the application form, the Lead Applicant must satisfy the conditions of this check list

Lead Applicant Eligibility	
I have read the Guidance Notes for the ILCT Programme 2025 Definitive Interventions stream and reviewed the main changes. **Please note, applications for a feasibility study should be submitted with the ILCT Feasibility study stream.**	☑
I am clear about the role of the authorized signatory in the nominated Host Institution**,** and I am aware that I need to build sufficient time into the application process for the HI to access, review and approve my final application for submission to the HRB through the GEMS system.	☑

Consent	
By submitting this application, I consent to (a) sharing of my data outside of the European Economic Area (EEA) for the purpose of international peer review, and (b) the use of my data for assessment of my application; monitoring of successful awards; and evaluation of HRB's approach to funding and investment in research, in line with HRB policies and as detailed in the ILCT Programme 2025 Call Guidance Notes.	☑

[13] https://research.ie/assets/uploads/2020/05/CCGT-Grant-Application-System-Technical-Guidance-Notes.pdf

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

Mandatory Requirements

Lead Applicant Declaration	
I confirm that the information provided is correct	☑
I confirm that any potential conflicts of interest have been declared in the section below	☑
I confirm that all HRB-funded trials will be registered in a publicly accessible register prior to initiation of the study and updated as necessary	☑
I confirm that trial results (positive or negative) will be submitted for publication	☑

Host Institution

The HRB expects applicants to contact their Host Institution and engage with them to facilitate a review of the application, including any institutional risk assessment. This is in particular to enable review of the application for detailed costings, and any approval of a sponsorship role.

For the purposes of contracting, payment, and management of the award, HRB funds can only be awarded to HRB approved Host Institutions. Please note this call is open for Host Institutions from the Republic of Ireland. The Host Institution for the award is normally that of the **Lead Applicant**, but it may be another organisation/institution designated by the research team, where it is clearly justified. In GEMS you will be asked to identify a Host Institution (from this list) and type it in full (do not use acronyms such as UCD, TCD, NUIG). Once you have entered the first 3-4 characters of the Host Institution, you will be assisted with auto-select options. It is important that the Host Institution name is entered accurately and in full as an incorrect entry may result in delays in attaining Host Institution approvals.

If you wish to propose a Host Institution which is not on the HRB list, you are advised to contact the HRB at gemshelp@hrb.ie.

Note: In order to be eligible to apply for funding, an Institution must have been approved as a HRB Host Institution no later than two calendar months before the closing date of a call, only pre-approved Host Institutions will appear in this list.

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 ILCT Programme 2025 Definitive Interventions stream. 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 Host Institution signatory** of your intention to apply as soon as possible in the application process. The signatory will receive an email

from GEMS with the name and email details of the Lead Applicant and if they have any queries or clarifications, they can engage directly to resolve them with the Lead Applicant. The Host Institution signatory must confirm their willingness to participate as Host Institution for the application through GEMS and once they do this a PDF of the application will be available for them to review with a view to them ultimately approving the final version for submission to the HRB.

Declaration of Interests

Please declare any conflict of interests or potential conflict of interest that a member of the applicant team may have, e.g., a personal or commercial interest in the research. Please give details where a member of the applicant team (including but not exclusively any industry partners) has previously been involved in the design and/or development of the product/service/application being researched (e.g., an App to deliver an education programme).

The Lead Applicant must ensure that they clearly and explicitly explain any potential and/or perceived conflicts, and how they will be managed by addressing the following issues within the relevant sections of the application form, e.g.:

- Clarity on governance arrangements.
- Clarity on roles and responsibilities.
- Necessary assurances in relation to access to data, IP and publication of results/findings.
- Any other important issue to be highlighted by the team.

The word limit is **400 words.**

1 Lead Applicant's Details

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

Host Institution Letters of Support must be provided for (1) all Lead Applicant in a contract position and (2) Researcher Co-Applicants in a contract position who are seeking their own salary. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre must include the following information; *[Host Institution – insert name] which is the Host Institution of [applicant – insert name]* confirms that *[applicant/co-applicant – insert name]*: (i) holds an employment contract which extends until *[insert date]* or will be recognized by the Host Institution upon receipt of the HRB ILCT 2025 award as a contract researcher; (ii) has a dedicated office and research space/facilities for which they is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team.

The Lead Applicant's **contact and CV** details (Name, institution, present position, employment history, profession, and ORCID iD) are managed in 'manage my details' section of GEMS and are automatically included in any application created involving that individual. You are asked to select your 10 most relevant publications for this application.

Note: The HRB is now an ORCID member. Lead applicants are encouraged to include an ORCID iD by updating their GEMS profile under 'Manage my Details' and this will feed automatically into the application form. You have also the option to import your publication record from ORCID iD in addition to PubMed. Please note this is not a mandatory field for submitting your application. For more information and to register please see https://orcid.org/.

Publications and Funding Record

In line with our commitment to the Coalition for Advancing Research Assessment and DORA, the HRB selection process is based on the **qualitative assessment of applications**. Applicant should not refer to metrics such as Journal Impact Factors, h-index or host institution ranking.

Publications are automatically included in any application created involving the Lead Applicant Researcher. To update this information, edit the 'My Research Outputs' section on the Home page of GEMS. You can then use the Publication selection tool in the relevant section of the application form to select your **most relevant publications** for this application.

You should also include your **5 most relevant funding awards** as Principal Investigator or Co-Applicant. For the purpose of this application form, Funding Record details should be added directly on to the application form and will not be pulled through from the 'manage my details' section of GEMS.

Additional evidence of experience and expertise relevant to this application

The Lead Applicant can describe any additional experience or expertise that will provide evidence of their ability to successfully lead the proposed project. This section focuses on the applicant contribution to the generation of knowledge, new ideas and hypotheses, and tools. This can include how ideas and research results were communicated (written and verbally), as well as funding and awards received. The word limit is **400 words**.

Note: Research outputs can include datasets, software, publications, commercial or entrepreneurial or industrial products, educational products, clinical practice developments, policy publications, and other similar items. These should be examples of rigorous science following high standards, that are reproducible, and others can build upon.

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

Breaks from research

In this section the Lead Applicant may want to mention breaks from research, such as statutory leave, secondments, flexible work arrangements or other relevant changes (e.g., sector or discipline) that may have affected or influenced their progression as researcher. Please state the period and the reason. The word limit is **150 words**.

Gender

Please select:

- Man
- Woman
- Nonbinary
- Another gender identity
- Prefer not to disclose

This question is included with the application form in light of the HRB Gender Policy. The HRB has the responsibility to support everyone to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. The information is for HRB internal use only.

2 Co-Applicants' Details

The Lead Applicant can add Co-Applicants to an application by entering their name on GEMS (up to a maximum of 15 co-applicants and collaborators in total).

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 decide whether to accept or reject their participation and **must 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 participation in an application will be able to edit the application. **The system will flag if another user is working on the application form at the same time via a pop-up warning. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data, but it is advisable that they contact the other person directly to avoid losing data when applying the override function.**

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

Co-Applicants will be asked to select whether they are a **Researcher Co-Applicant or PPI Contributor Co-Applicant** for the purpose of the proposed research. If a Co-Applicants contributes from more than one perspective, please select the dominant role. HRB strongly recommends the inclusion of a biostatistician as a Co-Applicant.

2.1 Researcher Co-Applicants

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

A**dditional evidence of experience and expertise relevant to this application**
The Researcher Co-Applicant can describe their contribution to the generation of knowledge, new ideas and hypotheses, and tools. This can include how ideas and research results were communicated (written and verbally), as well as funding and awards received. The word limit is **400 words**.

Breaks from research
In this section the Researcher Co-Applicant may want to mention breaks from research, such as statutory leave, secondments, flexible work arrangements or other relevant changes (e.g., sector or discipline) that may have affected or influenced their progression as researcher. Please state the period and the reason. The word limit is **150 words**.

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

2.2 PPI Contributor Co-Applicants

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

3 Collaborators

The Lead Applicant can add Collaborators to an application by entering their name on GEMS (up to a maximum of 15 co-applicants and collaborators in total).

Unlike Co-Applicants, the information for Collaborators is not automatically drawn from the 'Manage my Details' section of GEMS but must be entered by the Lead Applicant. The Lead Applicant must enter **contact and CV details** for all Collaborators including name, contact information, institution or organisation, present position, employment history, profession and membership details of professional bodies, **Publications and Funding Record** (if applicable) (**5 most relevant** publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) relevant to this application where the Collaborator has acted as Principal Investigator or Co-Applicant).

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

4 Study Details

4.1 Study Title

You are asked to provide a title that clearly describes the research to which this application is related. This should be descriptive and concise and should reflect the aim of the project. There is a **200 characters** maximum limit.

4.2 Acronym

Acronym is optional.

4.3 Research Question

4.3.1 Clearly state the research question behind the proposed work. The word limit is **100 words**.

4.3.2 Briefly explain the study phrased in PICO[14] terms, with reference to the **main research question** (as applicable to your study type):

- **P**opulation: target population
- **I**ntervention: represents the Intervention of interest
- **C**ontrol or comparison: Usually the standard intervention or no intervention
- **O**utcome: expected outcome, leading to effectiveness and cost-effectiveness

The word limit is **100 words.**

4.3.3 Have you searched the COMET database to check whether a Core Outcome Set (COS)[15] has been agreed for this area of health? Y/N

4.3.4 If a Core Outcome Set has been developed for this area of health, do you plan on using the existing COS? If not, please provide a rationale for not using the COS. The word limit is **100 words.**

4.3.5 Have patients or patient organisations been involved in the development of outcome measures for this study[16] (as appropriate) Y/N

4.4 Study Duration and Start Date

4.4.1 Please indicate the expected length of the proposed project in months. Please note maximum duration for definitive intervention studies is 60 months.

4.4.2 Please indicate the proposed start date

4.5 Study Lay Summary

[14] *Nobre MR, Bernardo WM, Jatene FB. Evidence based clinical practice. Part 1 - well-structured clinical questions. Rev Assoc Med Bras 2003 October-December; 49(4):445-9.*

[15] An agreed standardized set of outcomes that should be measured and reported, as a minimum, in all clinical trials in a specific area of health. www.comet-initative.org

[16] Plain language animation on outcome sets produced by COMET http://www.comet-initiative.org/resources/PlainLanguageSummary

This lay summary is similar to the Study Abstract in that you are asked to describe what you propose to do, why you think it is important and how you are going to go about conducting, analysing and drawing conclusions from the research. 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. It should not be copied and pasted from elsewhere in the application. The lay summary may be used when providing information to the public with regards to the variety of research funded by the HRB and may be posted on the HRB website. A well-written lay summary will enable peer reviewers and Panel members to have a better understanding of your research application.

Please provide a lay summary for the proposed research. The word limit is **300 words.**

4.6 Study Abstract

This should be a succinct summary of the proposed research. This structured summary should clearly outline the background to the research, the aims and hypotheses of the project. The objectives of the project and what the work is expected to establish should be described. It provides a clear synopsis of your application and should set the research application in context.

Please provide an abstract for the proposed research. The word limit is **300 words**.

4.7 Study Type

Please note, this application stream is for **definitive interventions only**. For feasibility studies, please submit via the Feasibility Study stream of the ILCT Programme 2025.

4.7.1 Please select a study type

- Definitive Intervention
- Definitive Intervention & **Methodology sub-study** (including SWAT)

4.7.2 Is this a regulated or non-regulated study?

- Regulated study
- Non-regulated study

4.7.3 Is this a multicentre study? Y/N

Is Yes, please list all the study sites below. Please also indicate the recruitment target at each site.

Site	Recruitment target

4.7.4 Is this an international study Y/N

4.8 Keywords

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

5 Study Description

Please ensure that this section is focused, and that sufficient evidence is provided to enable the international peer reviewers and grant selection panel members to reach a considered judgement as to the quality of your research application, its potential health impact and its feasibility.

5.1 Relevance and Rationale for Proposed Research

Describe the background to the research proposal and detail the size and nature of the issue to be addressed. The word limit is **1500 words.**
Please address the following:

- State the principal research question being asked.
- What is the rationale for the study?
- Why is this intervention needed? What problem is being addressed? Justify the necessity for the research, both in terms of timeliness and relevance to health of patients/public/health system especially in an Irish context.
- Please address potential benefits and potential harm of the proposed intervention.
- Will the results be generalizable beyond the research setting of the study?

5.2 Description of the intervention

Please describe the intervention you are proposing to trial. The description should include the theoretical basis underpinning the intervention. The word limit is **500 words.**

Note: A logic model outlining the model/theory for change for the implementation of the intervention can be uploaded. This diagram should be submitted as a pdf.

5.3 Are any relevant studies listed on international registries?

Such as Clinical trials.gov, European Clinical Trials Database (EudraCT) and/or International Clinical Trials Registry Platform (ICTRP). If yes, please provide study registration number(s). The word limit is **200 words.**

5.4 Description of the systematically gathered evidence base

Evidence synthesised systematically to include evidence of (i) a systematic identification of previous work, (ii) critical appraisal, (iii) synthesis of the evidence and (iv) interpretation of findings. Demonstrate why your research is important now, both in terms of time and relevance. Where no relevant published systematic review exists, it is expected that the applicants will undertake a satisfactory review of the currently available evidence using systematic techniques. Simple literature overviews are not sufficient. Applicants must provide a protocol to show how the search was conducted, including literature and clinical trials registries.

The proposed standard for what constitutes a satisfactory review of the existing evidence to inform your research proposal is as follows:

- A relevant Cochrane Systematic Review **or**

- If no Cochrane Review exists, then another systematic review that is published in a peer reviewed journal **or**
- If no published systematic review is identified, then the Lead Applicant and research team should present the findings of a systematic review that they have undertaken for the purposes of the application. Importantly, in this case applicants are required to provide sufficient details of the methodologies employed to allow evaluate confidence in the findings and to allow the review to be replicated. Simple literature overviews are not sufficient.
- Additional evidence may be provided through formal input from relevant Irish patients, service users or carers. However, this does not substitute for systematically gathered evidence.

Please describe the systematically gathered evidence base for this research. The word limit is **750 words.**

5.5 Evidence from previous feasibility studies

Include relevant information from previously conducted feasibility studies. The word limit is **500 words. Please note, this is compulsory for applications to the definitive intervention stream.**

Please address all the following:

- Describe clearly but succinctly the work that was carried out, when, on what groups in which settings and what was learned that facilitated the development of the protocol for the final definitive study.
- Provide details on the screening and recruitment rates achieved during the feasibility study.
- Were progression criteria met?
- Provide assurances that you are confident that the intervention can be consistently implemented as intended.

5.6 International Study

Is the study part of a larger International Study? Y/N

If Yes, please upload the full protocol and provide a summary of progress to date. If the study is live, please provide a letter from the Chair of the Independent Data Monitoring Committee (IDMC) outlining how the recruitment is progressing and any issues that may be relevant for reviewers.

If your proposal is to add Irish sites to an international study, please make a clear case for undertaking this study in an Irish setting. State with clarity the projected recruitment numbers for the trial overall, and the projected recruitment numbers from Ireland (at the sites listed in sections 4.7.3). Clarify the funding status of the main study, whether it is powered adequately without the Irish component, and clearly articulate how participation from Ireland will add value to the study (e.g. by increasing generalisability to different healthcare settings, including a different sub-population etc.).

Clearly outline what the role of the participants from Ireland will be in the context of the International study (aside from recruitment), and what role the international lead/partner will take in relation to the study in Ireland. The word limit is **500 words.**

5.7 Overall Aim

Please state the overall aim of the research project. The word limit is **150 words.**

5.8 Objectives and Deliverables

Please add a minimum of 3 research objectives. Objectives should be SMART (**S**pecific, **M**easurable, **A**chievable, **R**ealistic and **T**ime-bound). For each objective, list a subset of deliverables which will be used to monitor progress throughout the lifetime of the award if successful. Objectives/deliverables should be mapped against estimated completion timelines in a Gantt chart, and any milestones highlighted.

The word limit is **60 words for each objective and 150 words for the deliverables**. Please use the 'Add objective' function to add each objective one by one.

You must upload a **Gantt chart** which lists the above objectives and deliverables against the estimated timelines for completion, together with any additional milestones/key dates. Please note that the preparation and submission of Data Management Plans should also be added as deliverables/milestones of the Project.

Note: Two Deliverables for a Data Management Plan must be included: one at study start, one at the end of the study.

5.9 Research Design and Methodology

Summarise the proposed research plan, providing descriptions of individual work packages and describe how they integrate to form a coherent research application. The word limit is **5000 words.**

Include details of the general experimental approaches, study designs and techniques that will be used. Include details of the general experimental approaches, study designs and techniques that will be used. Include details on all stages of the study design including rationale for sampling strategy, justification of sample size and power calculation, details on the design chosen and the intervention, the methods of data collection, measures, instruments and techniques of analysis for quantitative and qualitative designs, outcomes measures, cost effectiveness and data analysis/management plans as appropriate.

Please clearly describe the **healthcare setting** and **how participants will be accessed** as all reviewers will be from outside the Irish healthcare system.

Justify the **choice** of your planned intervention. Please consider following the TIDieR[17] checklist and guide for describing the intervention.

Describe and justify the **design** chosen, the methods you plan to use and the rationale of your choice. Show how your research design will allow you to answer your research question. **You are expected**

[17] *Hoffmann T et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687*

to seek advice and input from an experienced research design and statistics expert at study design phase.

Please address the following and consider reviewing Appendix II:

- What is the proposed study design (e.g. randomised or non-randomised, conventional parallel group RCT as opposed to cluster, factorial or stepped-wedge design etc.)?
- Describe the population to be studied
- Please consider the age and gender of participants and clearly justify exclusions
- Is subgroup-analysis by gender planned?
- Briefly explain sex and/or gender issues in this study
- Do the proposed subjects represent your target population?
- What is the planned intervention?
- Have you fully described 'usual care' (if appropriate)?
- Describe the healthcare setting in which the intervention will be delivered
- What are the proposed practical arrangements for allocating participants to study groups?
- What are the proposed methods for protecting against sources of bias?
- How variable is the intervention – between sites, over time etc.?
- Are there aspects of context and/or the environment which may impact on the evaluation being undertaken?
- What are the planned inclusion/exclusion criteria?
- What is the proposed duration of intervention period?
- What is the proposed frequency and duration of follow up?
- Discuss the reliability and validity of all study instruments and scales for the intended population
- What are the proposed primary and secondary outcome measures? For surrogate outcome measures, provide evidence of validity. Was patient/patient representatives input sought in relation to the outcome measures?
- Show how the outcome measures chosen will ensure clinical relevance as well as relevance for the patient/target population.
- How will the outcome measures be measured at follow up?
- Are you planning to include health economics and quality of life measures? If yes, provide full details regarding the type of analysis to be undertaken, the rationale of the design proposed, the personnel who will conduct analysis, power calculations and inclusion/exclusion criteria. In cases where one or both of these measures will not be addressed in this study, please explain why.
- What size of the difference is the trial powered to detect?[18]
- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include for both control and intervention groups, a brief description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate
- What is the planned recruitment rate? How will the recruitment be organised? Over what time period will recruitment take place?
- What evidence is there that the planned recruitment rate is achievable?

[18] As appropriate, see J Cook et al. *DELTA2 guidance on choosing the target difference and undertaking and reporting the sample size calculation for a randomised controlled trial* https://www.bmj.com/content/363/bmj.k3750

- Are there likely to be any problems with compliance? On what evidence are the compliance figures based?
- What is the likely rate of loss to follow up? On what evidence is the loss to follow-up rate based?
- How many centres will be involved (specify national and international as appropriate)?
- Has acceptability testing been considered?
- What is the proposed type of analyses?
- What is the proposed frequency of analyses?
- Are there any planned subgroup analyses?
- Do you plan a process evaluation?

The HRB encourages the development and application of agreed standardised sets of outcomes, known as 'core outcome sets', such as those reported by the COMET (Core Outcome Measures in Effectiveness Trials) Initiative. **Applicants must search the COMET database when considering which outcomes measures to include**[19]

- You are advised to carefully address the potential benefits and difficulties presented by multi-site recruitment of patients or human subjects for the study in order to reach recruitment targets.
- Explain in detail how new techniques and/or or high-risk studies will be managed and suggest alternative approaches should these fail.
- Where new methods are being developed, arrangements for establishing validity and reliability should be described. Examples of non-standard questionnaires, tests, etc. should accompany the application or their content be clearly indicated.
- Useful links and resources are summarised in Appendix IV.

5.10 Internal Pilots

Internal pilots designed at the early stage of a definitive intervention trial can be included in the main study only where robust feasibility work has been completed and indicates that an internal pilot is appropriate. Details should be provided in Section 5.5 "Evidence from previous feasibility studies".

Internal pilot studies designate a portion of the main trial as a pilot phase. At the end of the internal pilot study, the investigators re-compute preselected parameters and recalculate required sample size. The study then proceeds with the modifications dictated by the internal pilot. Final analyses of the results incorporate all data, disregarding the fact that part of the data came from a pilot phase. Those conducting pragmatic trials may wish to consult a published checklist to aid decision-making on whether pilot data can be carried forward to the main trial.[20]

Please note: As part of the Monitoring and Evaluation Framework for Investigator Led Clinical Trials, recruitment and other parameters/activities in the study will be monitored biannually by the HRB.

[19] www.comet-initiative.org

[20] *G. Charlesworth et al. ACCEPT Acceptance checklist for clinical effectiveness pilot trials: a systematic approach. BMC Medical Research Methodology 2013 13:78*

Are you planning to include an internal Pilot? Y/N

If yes, please provide details below. The word limit is **500 words.**

5.11 Participant flow diagram

Please upload a flow diagram showing the study design and the flow of participants. You should refer to the appropriate diagram depending on your study design (e.g. CONSORT for RCTs). Please see Appendix IV for some useful links. This diagram should be submitted as a pdf and be clear as it will be referred to, and likely viewed on screen during the Panel discussion.

5.12 Go/No Go Progression Criteria

Go/No Go criteria within the trial are a method to help to determine whether an ongoing trial is feasible to continue. Please specify and provide a justification for appropriate Go/No Go and Progression criteria and the timelines for their implementation for your study:

- For the individual participant
- For participating centres, which fail to include the estimated number of participants and
- For the whole trial

For example:

- Year 1 - expected recruitment = 50, Go/No criteria = 5
- Year 2 - expected recruitment = 80, n Go/No Go criteria = 30
- Year 3 - expected number of participating centres = 5, Go/No Go criteria = 2

Please describe how these criteria will be overseen by the appropriate governance committee. The word limit is **400 words.**

Please Note: Go/No Go and Progression Criteria for the most important/fundamental targets to the success of the study should only be included. These criteria will be reviewed as part of the post-award reporting and monitoring of successful grants by the HRB.

5.13 Methodology sub-study (including SWATs)

Applicants are encouraged to include an embedded trial methodology sub-study within their trial proposal. This sub-study may take the form of a Study Within A Trial (SWAT)[21] or other approach focused on improving the design, conduct, analysis, reporting, or dissemination of trials in areas where there is current uncertainty. Please see recently published guidance on how to decide whether a further trial **methodology sub-study** is merited on the particular question[22].

[21] S Treweek et al. *Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)?* https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2535-5

[22] S Treweek et al. *Trial Forge Guidance 2: how to decide if a further Study Within A Trial (SWAT) is needed* https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3980-5

5.13.1 Are you planning to include a trial methodology sub-study? Y/N

5.13.2 If Yes, provide full details on the following:

- A clear description of the trial **methodology research question** and its importance.
- The **rationale** for the sub-study design (e.g., randomisation, outcomes, feasibility).
- Details of the **personnel** involved and their expertise.
- Any **power or sample size** calculations, if applicable.
- A short **analysis plan** with proposed endpoints or measures of success.
- **Inclusion/exclusion criteria** (if different from the main trial).
- The **added value** of this sub-study to both the main trial and future trials.

Please refer to existing guidance, such as that available from **Trial Forge**, and to the **SWAT Repository Store** (Northern Ireland Network for Trials Methodology Research), to confirm whether a similar methodology question has been addressed previously[23]. Unnecessary duplication should be avoided unless clearly justified.

Note: Trial Methodology sub-studies should be conducted to the same high standard as the main trial (e.g. having a written protocol and plan for dissemination).

An additional €20,000 (inclusive of overheads) in funding can be requested for conducting a trial **methodology sub-study**, in addition to the overall budget. The word limit is **750 words.**

The HRB-TMRN may provide support for developing primary trial methodology sub-studies. Please see **https://www.hrb-tmrn.ie/support/grant-application-support/** for their specific deadlines. See Appendix IV for relevant resources on SWATs and further trials methodology research.

5.14 Public and Patient Involvement (PPI) in the Research Project

*The HRB recognises that the nature and extent of meaningful public involvement is likely to vary depending on the context of each study. Please note PPI does **not** include the recruitment of study participants in research projects. It also does **not** include work aimed at raising awareness of the public around research, such as media publications of research findings, and outreach activities such as open days in research facilities.*

Useful resources including practical examples of involving members of the public in your research can be found in Appendix IV. Please be aware there are PPI Ignite Network offices in some host institutions.

Are you including PPI in your application? Y/N

If Yes, please describe all PPI at each stage of the research cycle:

- Identifying and prioritising the research question
- Design
- Conduct
- Analysis
- Oversight

[23] https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/Repositories /

- Dissemination

The word limit is **600 words**.

For each stage, please include the purpose of this involvement and where applicable how PPI has influenced/changed what work has been planned. This section should be a succinct summary of public involvement activities. Provide information on the individuals/groups and the ways in which they will be involved. PPI contributors should be representative of the relevant people and communities impacted by the research topic. **Where members of the public or patients are involved, they should be compensated for their time and contributions; this should be reflected in the project budget.**

Please ensure to provide more detail in other sections as appropriate.

Important: The PPI section 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.

If No, please explain with PPI is not relevant to your project.

5.15 Impact Statement

The statement should be as specific as possible and provide information that reviewers will find helpful in assessing the potential impact of the proposed research activity. An implementation plan that outlines the pathway to impact citing realistic timelines is requested.

Please provide details on the likely impact from the proposed research on patients, public and/or healthcare system and articulate the pathway by which the research will achieve this. By "Impact" we mean the direct contribution to improvements/benefits to patient care, health of the public and health services from this research in the short to medium term (1-5 years after the end of award). Where impact is mainly anticipated in an Irish context, please describe this for international reviewers and Panel members. The word limit is **500 words.**

5.16 FAIR Data Management and Stewardship

Describe the general approach to data management and stewardship that will be taken during and after the projects, including who will be responsible for data management and data stewardship. With the support of data stewards or other data-related services support in the institution (typically library and ICT and digital service, etc) all Applicants should address as much as possible the following points below regarding the management of the research data to be generated and/or re-used during the research project.

Please consider the FAIR Guiding Principles for scientific data management and stewardship: **F**indability, **A**ccessibility, **I**nteroperability, and **R**eusability[24].

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

1. **Data description and collection or reuse of existing data**: (a) What is the type, format and volume of data? (b) How will the data be collected, created or reused?
2. **Documentation and data quality**: (a) What metadata and documentation will accompany the data? (b) Will you make sure globally resolvable unique, persistent identifiers are in use (e.g DOI)? (c) What data quality control measure do you use?
3. **Storage and backup**: (a) How will data be stored and backed up during the research? (b) How will you take care of data security and personal data protection?
4. **Ethical and legal compliance, codes of conduct**: (a) If personal data are involved, how will you manage compliance with legislation on personal data and security? (b) How will you manage legal issues, such as IPR, copyright, and ownership? Which legislations are applicable? (c) Which ethical issues and codes of conduct are there and how are they taken into account?
5. **Data sharing and long-term preservation:** (a) How and when will you share the data? (b) How do you select data for preservation and where will data be preserved long term (e.g. data repository, archive)? (c) What methods or software tools are needed to access data? (d) How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?
6. **Data management responsibilities and resources:** (a) Who (for example role, position, and institution) will be responsible for data management (i.e., the data steward)? (b) What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR?

Please describe the approach to data management and stewardship that will be taken during and after the project. The word limit is **500 words**.

5.17 IP Considerations

The Lead Applicant together with the Host Institution has a duty to the public to ensure that discoveries and advancements in knowledge arising from any award are translated for public benefit including but not limited to commercial development of new therapies, diagnostics, materials, methodologies, and software for health[25]. Please consult with the relevant Technology Transfer Office for advice on this section, where appropriate.

Please describe any current Intellectual property (IP) that will be relevant for the study and whether such IP assets are held by the applicants, and/or others outside the research team. Such IP might include software, checklists, scales, protocols, guidelines, questionnaires, or medicinal products for example. Has relevant background IP for your study been identified? If IP is required, is there freedom to operate, such that this research can eventually be translated? What arrangements are in place to manage IP during the study, and ensure it is protected (if appropriate) prior to dissemination? Do you foresee any barriers to use of IP in order for the research outputs to be adopted?

[25] Ireland's National IP Protocol 2019: A Framework For Successful Research Commercialisation: Policies and resources to help industry and entrepreneurs make good use of public research in Ireland

Please describe any current IP that will be relevant for the study and whether such IP assets are held by the applicants, and/or others outside the research team. The word limit is **500 words**.

5.18 Trial Management, Governance and Safety Monitoring

The HRB requires that all clinical trials and interventions have the appropriate governance arrangements in place before a trial can begin. Arrangements for the management of the trials will vary according to the nature of the study proposed and should be proportionate to the complexity and associated risks. However, all should include an element of expert advice and monitoring that is **entirely independent** of the Lead Applicant, research team members and the institutions involved. Typically, definitive trials are overseen by three committees[26]: a Trial Management Group (TMG) a Trial Steering Committee (TSC) and an Independent Data Monitoring Committee (IDMC).

Applicants should describe an appropriate oversight and governance structure for their trial.

- Describe the appropriate oversight, advisory or governance structures that will be established to oversee and monitor this trial, e.g. Trial Management Group (TMG) a Trial Steering Committee (TSC) and an Independent Data Monitoring Committee (IDMC)
- Describe the function/role of each Committee/Group
- Describe role of the group members (e.g. sponsor, principal applicant, coordinator, trial statistician, research personnel, collaborators, CRFs) in the day-to-day management of this study, for all aspects of the study including recruitment, randomisation, management and retention of biological samples, delivery of intervention, follow-up, data entry, quality assurance, data management and analysis.
- Provide details of the membership of the proposed Committees/Groups, including the proposed Independent Chair (as appropriate) where known.
- Outline the processes that will be put in place to ensure that the trial is well managed, commenting on project management, meeting schedules, financial management and monitoring etc.
- If the study is multi-site, or multi-site and international please state any additional measures that will be undertaken to ensure the study is well managed.
- Please list anticipated risks to the successful delivery of the study and how it is planned to mitigate against those risks.

Please detail the proposed arrangements for overseeing the trial. The word limit is **2000 words.**

Note: The Terms of Reference for these groups will be requested as part of HRBs post award monitoring of successful grants.

[26] https://www.nihr.ac.uk/funding-and-support/documents/funding-for-research-studies/how-to-apply/NETSCC_Project_Oversight_Groups_Guidance.pdf

5.19 Potential safety risk and ethical concerns

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

Please address any potential safety risk and ethical concerns. The word limit is **500 words.**

5.20 Biobanking

Does your application include an element of formal biobanking? Y/N

If Yes, please describe how biobanking within this project will be in compliance with international best-practice ethical considerations and the General Data Protection Regulation, in particular in relation to consent.

You must submit a completed **Infrastructure Agreement** form with details of the formal biobank. Please describe how you will ensure good practice for biobanking components in this project, with particular regard to quality of sample collection, processing, annotation and storage. Please reference relevant guidelines/standards you will use. Where material will be obtained or stored for a future research purpose, or where you will use material previously obtained for another purpose, please refer to the latest Recommendation of the Council of Europe[27]. Some useful links are in Appendix IV.

Please note: If you are planning to collect samples and preform sample analysis this should be described in the Section 5.9. The word limit is **400 words.**

5.21 Gender and/or Sex Dimensions within the Research Project

A key objective of the HRB is to strive for gender balance in Irish health research. We encourage a balanced participation of genders in all research activities. Please see Appendix IV for resources on gender and sex considerations in research applications.

Please note this section is intended to focus researchers on the **research content**, and **not** the gender balance within the research team.

Are there potential sex (biological) considerations for this research?

Are there potential gender (socio-cultural) considerations for this research?

If so, outline how sex and/or gender analysis will be integrated in the design, implementation, evaluation, interpretation, and dissemination of the results of the research application.

If not, you must clearly demonstrate why it is not relevant to the research application; have you done a literature search to confirm this?

[27] https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

Please identify and explain how you address sex and/or gender issues in your research. The word limit is **400 words.**

5.22 Inclusion of underserved groups

Please describe how you propose to engage with, and improve inclusion of, under-served groups specific to your study and its context. Outline how inclusion of these groups will be integrated in the design, implementation, evaluation, interpretation and dissemination of the results of the research proposal.

The following groups may be underserved depending on the study and its context*

- Groups by Demographic Factors (Age, Sex, Ethnicity, Education)
- Groups by Social and Economic Factors
- Groups by Health Status
- Groups by Disease Specific Factors

** please note the list of groups is not exhaustive*

The word limit is **500 words.**

Please see Appendix IV for information on how to engage in a structured way with groups that may be under-served by trials and interventions inclusion in your area of research.

5.23 Dissemination and Knowledge Translation Plan

Include a clear dissemination and knowledge translation plan to indicate how the research outputs you anticipate producing during and after your project will be disseminated and shared and made openly accessible, in line with HRB Open Access Policy[28]. Research outputs include peer-reviewed publications, non-peer reviewed publications and conference proceedings, reports, policy briefings, guidelines, training materials and so on. Protection of Intellectual Property should be considered before data are disseminated[29].

Applicants are advised to consider the following:

- The HRB has a mandatory Open Access publication policy; demonstrate how you plan to make all publications open access.
- Who are the various audiences and communities that need to be targeted if these results are to have any impact? What is your dissemination plan to address this, how will these audiences be reached?
- Describe any plans for technology transfer.

[28] https://www.hrb.ie/wp-content/uploads/2024/10/Open-Access-to-research-publications.pdf

[29] All HRB Host Institutions must subscribe to the National Intellectual Property Protocol 2019, 'A Framework For Successful Research Commercialisation', prepared by Government/Knowledge Transfer Ireland to ensure transparent and consistent procedures for managing Intellectual Property from publicly funded research.

- Describe how the findings of this research will be publicised to the HSE or international health community/organisations in a manner that will optimise impact on health policy and/or practice.
- Please reference aspects of the project/study undertaken to maximise chances of adoption beyond the term of the grant.

Types of publication routes include[30]:

Green Route: publishing in a traditional subscription journal. Articles are 'self-archived' (added) to a repository (institutional or external subject-based) and usually made available after an embargo period, which is set by the publisher.

Gold Route: publishing in an open access or hybrid journal. Articles' processing charges (APCs) are required so that the article is openly available immediately on publication and can be added to a repository (institutional or external subject-based).

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

The word limit is **500 words**.

5.24 Communication with Research Participants

Briefly describe how you plan to communicate with research participants during the study and once results of the study are known. Please give details of how you plan to do this, who will communicate with participants, and at what intervals communication will occur. The word limit is **200 words**.

5.25 Study Description Figures

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

Additionally, a draft protocol can be uploaded, if available.

5.26 References

A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of **30 publications**. Please enter references in the same format.

For publications:

[30] https://www.jisc.ac.uk/our-role-in-open-access

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

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

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

6 Details of Research Team

6.1 Expertise of the Research Team

The research team should include the necessary expertise and experience to carry out the study. Please describe how the team has the collective expertise, competencies and experience to successfully deliver this particular study, under the leadership of the Lead Applicant. In particular describe how research design methodological expertise including statistical expertise has been sought and incorporated within the team.Include reference to relevant publications from team members specifying their role in ongoing or previous trial(s) as appropriate. The word limit is **600 words**.

6.2 Lead Applicant's Role

Please indicate the current commitment to research/clinical/teaching/other as proportion of a full time equivalent (FTE).

Give an outline of the proposed role of the Lead Applicant in this project on a day-to-day basis. Please indicate below the proposed amount of time to be dedicated to working on **this project** as a proportion of a full time equivalent (FTE). The word limit is **250 words.**

6.3 Co-Applicant's Role

For each Co-Applicant, please identify the type of Co-Applicant they are here (Researcher Co-applicant or PPI Co-applicant) and outline their role in this project on a day-to-day basis, including the amount of time to be dedicated to working on this project as a proportion of a full time equivalent (FTE). HRB strongly recommends the inclusion of a biostatistician as a Co-Applicant. The word limit is **250 words**.

6.4 Collaborator's Role

For each Collaborator, please outline their role in the project. The word limit is **100 words**.

6.5 Personnel

Give full details of all personnel to be funded through this project, including the Lead Applicant if relevant. State the proportion of a full time equivalent (FTE) each person will spend on the project and describe what aspects of the proposed research they will be involved in over the lifetime of the project. Note that you must justify the nature of all research personnel relative to the scale and complexity of the project. If funding is requested for known personnel, please include the following details: Name, present position, academic and professional qualifications. The word limit is **400 words**.

Note: this scheme is **not framed as a training initiative**. The required expertise, risks and dependencies inherent in clinical trials do not align well with the needs of those registered for a higher degree. Thus, **no PhD/MSc will be** funded through the ILCT Programme.

7 Infrastructure and Support

7.1 Host Institution Infrastructure and Support

Describe the infrastructure, facilities, specialist expertise and other support available at the Host Institution and/or at other sites where the research will be conducted. The word limit is **400 words**.

Please include details of critical supports in areas such as statistics, research methods, biobanking expertise or regulatory expertise where this is being provided above and beyond the activities/expertise of members of the research team.

7.2 Access to Research Infrastructures

Applicants are expected to avail of the advice, trial and data management services and/or other forms of support from existing research infrastructures such as a Clinical Research Facility/Centre (CRF/C), the HRB Trials Methodology Research Network (HRB TMRN[31]), a thematic HRB Clinical Trials Network (HRB CTN) or Cancer trials in Ireland Groups, or the National Cancer Clinical Trial Network.

Please provide an overview detailing the scope and nature of the engagement (this includes national facilities and/or international facilities and Units/networks as appropriate to the proposed study). Applications which do not detail such input, advice and/or support (and where this expertise is not clearly evident within the applicant team) should justify why they have chosen not to access such support. The word limit is **500 words**.

Please note: In line with the HRB Clinical Trials and Interventions Research Governance Policy **Regulated clinical trials** such as a clinical trial of an investigational medicinal product or a clinical investigation **must be conducted under the governance of a Clinical Research Facility/Centre (CRF/C)**, evidence of which must be provided to HRB in the form of an Infrastructure Agreement Form.

Applicants need to provide an **Infrastructure Agreement form** (including national and international infrastructures as required) setting out the following information:

[31] Support by the HRB-TMRN requires the inclusion of a primary methodological study within a trial (e.g. SWAT) or must include a non-standard novel trial design

- Name and address of the infrastructure
- Web links
- Information on the nature and stage/s of the input/advice/collaboration/service
- Rationale for the choice of infrastructure
- Information on the costs of providing the service/input, setting out where this is provided in-kind, from additional funding or requested from the project budget
- Any issues related to feasibility

An Infrastructure Agreement Form can be downloaded from the Infrastructure and Support page of this GEMs application and must be completed for each support service involved. The Form must be completed, signed, dated and uploaded on GEMs. For regulated clinical trials, the Form must be signed by the CRF/C Director. Electronic signatures are acceptable for letters/forms that are uploaded on GEMs. **Applicants must take note of the individual deadlines for application for support from the various infrastructures and contacting these infrastructures should be done as early as possible to avoid capacity issues.**

8 Project Budget

Please provide a summary and justification of the costs and the time associated with the project. The DI stream of the ILCT Programme scheme will provide funding for Definitive Intervention studies up to a maximum of **€1,300,000** (inclusive of overheads) (or €1,000,000 direct costs) per grant.

An additional **€20,000** (inclusive of overheads) can be applied for if conducting a methodology sub-study (relating to trial methodology research only)[32]. **There is no set limit per annum** therefore the proposed budget per annum should reflect anticipated annual costs.

The budget requested and award duration must reflect the scale and nature of the proposed research and reviewers will thoroughly assess the level of funds and timeframe requested when reviewing the proposal. Please note: salaries should be commensurate with the role and expertise requirements and be fully justified in the context of the specific trial.

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

Note: You are strongly advised to seek guidance from the research office/finance office in the Host Institution before completing this section of the form. The HRB will not provide additional funding in the case of either under-estimates or over expenditure**.**

Please refer to the HRB-NCTO Budget Checklist for Clinical Trials Costs for guidance on clinical trial costs. Some costs listed in the HRB-NCTO checklist are not eligible for HRB funding (e.g. salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits). Additionally, the HRB does not provide salary or buy out time for collaborators.

[32] Please note that individual proposed m**ethodology sub-study/** SWATs may cost more or less than €20,000; actual costs should be included. The additional budget allowance for **methodology sub-studies** is to encourage and support further m**ethodology sub-studies** within the HRB-funded portfolio.

Allowable costs include:

1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with Host Institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scales for academic researchers http://www.iua.ie/research-innovation/researcher-salary-scales/.Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure. **Applicants should include annual pay increments for staff and related costs (pension contribution and employer's PRSI contribution) in the budget.** In line with the proposed new pay agreement for State employees please apply a salary contingency of 3% from 1st October 2024 onwards. Please note this contingency should be applied cumulatively year on year. **Note:** The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators
b) Employer's PRSI	Employers' PRSI contributions are calculated at a % of gross salary. Please confirm the correct PRSI % rate with your institutional finance office.
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). If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, data access costs etc. **Please consult with your Host Institution in relation to trial-related insurance costs.**

	Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, Clinical Research Facilities support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form'. The following costs are ineligible and will not be funded: training courses/workshops with the exception of GCP training and training in public and patient involvement in research, 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. PPI Costs	Costs associated with public and patient involvement in research. Some examples are:
	
	• Compensating PPI contributors for their time (for example for time spent reviewing material/ participation in advisory groups). This can be as:
	  ○ a cost for their expertise, e.g. as hourly rate, under PPI costs or
	  ○ as salaries under personnel which should be labelled PPI contributors under salaries.
	• Travel expenses for PPI contributors.
	• Costs associated with PPI contributors attending conferences, workshops, or training.
	• PPI facilitator costs.
	• Compensation of public or patient organisations for their time.
	• Room hires for PPI events/meetings.
	• Hospitality for PPI events/meetings.
	• Companionship or childcare costs for PPI contributors while attending events, meetings, etc.
	• Training in PPI in research.
	• PPI contributors supported by salaries as research staff or co-applicants, where applicable in a scheme, should be listed and justified under the personnel heading.
	
	All costs must be in line with the Host institutions policies, practices and HRB Terms and Conditions.

4. Equipment	Funding for suitably justified equipment can be included in this section. HRB does not expect equipment costs in excess of €10,000. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e., overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified, and should not exceed €1,200. All costs must be inclusive of VAT, where applicable. Depending on the nature of the project, high spec computers may be eligible and clear justification and rationale for the costs requested must be provided. All costs must be inclusive of VAT, where applicable.

5. FAIR Data Management Costs	Costs related to data-related and data management activities in line with best practice of data management and stewardship and the FAIR principles **incurred during the lifetime of the project**. Please see table below for further guidance.
6. Dissemination Costs	Please list dissemination costs under the following categories: conferences, other activities (expanded as necessary). Costs associated with seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge translation plan, as well as costs related to data sharing. **Conferences:** We envisage that conference costs will be typically around €500 for national conference and €1,500 for international conference per person and year.
7.Open Access Costs	Costs associated with publication of results, Please refer to the HRB policy on Open Access to Published Research[33].Typically, the average HRB contribution towards publication costs is €1,750/per article or **HRB Open Research**: rapid open peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee (www.hrbopenresearch.org) free of charge. Open Access costs should be included as a separate budget category on GEMS.

Overhead Contributions. In accordance with the HRB Policy on Overhead Usage[34], the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes postgraduate fees, equipment, and capital building costs) for clinical trials.

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. Therefore, these should not be included in the budget as direct costs.

8.1 Use of Resources

Please demonstrate that the resources requested, plus other in-kind resources where applicable, are sufficient to successfully deliver this study, to target and on time. Please explain how good use is made of the budget requested, sharing resources where it is appropriate. The reviewers will carefully assess costs within the HRB budget for e.g. drugs or devices to be used, so this should be justified in this section. The word limit is **200 words**.

8.2 Additional guidance to FAIR Data Management Costs

[33] https://www.hrb.ie/wp-content/uploads/2024/10/Open-Access-to-research-publications.pdf

[34] https://www.hrb.ie/wp-content/uploads/2024/09/HRB-Policy-on-Use-of-Overheads-V1.0-2015.pdf

People	Staff time per hour for data collection, data anonymisation, etc
	Staff time per hour for data management/stewardship support, training, etc
Storage and computation	Cloud storage, domain hosting charge
Data access	Costs for preparing data for sharing (e.g., anonymisation)
Deposition and reuse	Costs for depositing research data and metadata in an open access data repository
	Defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please further explain

Notes	The HRB is currently not covering the cost of long-term preservation of data
	This list is not exhaustive and aims to provide examples only of eligible costs

9 History of Application and Other Funding

9.1 History of the application

Has an iteration of the proposed research been submitted to any HRB award scheme in the last 3 years, including the ILCT Programme 2025? Y/N

If yes, please provide the following details:

Award Scheme:

Year of previous submission:

Please briefly describe the changes that have been made to the application. Describe how the feedback or recommendations from the previous peer, panel, or public review have been incorporated into the current proposal.

Please note: Proposals can only be resubmitted once to subsequent deadlines in the ILCT Programme 2025 (i.e. submitted twice in total)

In instances where a previous proposal related to the current application was funded, please outline how it contributed to the progression of the research. Where supplemental funding is sought through the ILCT Programme for a previously funded study, the rationale for this needs to be clearly articulated and well justified. The word limit is **500 words**.

9.2 Other Funding Sources

Please indicate if you have submitted this, or a similar application, to another funding body. If this application has been submitted elsewhere, please indicate which funding body, project title, result of submission or when outcome is expected and the amount of award. The word limit is **200 words**.

9.3 Other Financial Support

Give details of any other financial support or in-kind support available for this or any other related project e.g. existing national or international studies or co-funding from partner organisations. Indicate project title, funding agency, partner organisation or sponsor and the amount of award/co-funding. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review. The word limit is **200 words**.

9.4 Co-Funding Budget Commitment

If applicable, please include details on any co-funding commitment and indicate the total amount secured from this Co-Funding. The word limit is **400 words**.

Co-Funding Commitment Letter

Please note that a Co-Funding Commitment Letter must be uploaded where co-funding is part of this application. This letter should confirm that the funding contribution is in place. It is not a mandatory application requirement to secure co-funding.

10 Ethical Approval, Regulatory Approval and Sponsorship

Please note, all clinical trials funding through the DIFA and ILCT Programme funding schemes must adhere to the HRB Clinical Trials and Interventions Research Governance Policy, which sets out requirements for approvals and contracts, sponsorship, insurance, trial registration and publication of trial results.

10.1 Ethical Approval details

Ethical approval is required for all research work funded by the HRB that involves human participants.

10.1.1 From which Research Ethics Committee(s) will you seek ethical approval?

10.1.2 What is the likely date for receipt of this approval?

10.1.3 Are you uploading a copy of the REC approval with this application? Y/N

10.2 Regulatory Approval details

Regulatory Approval from the Health Products Regulatory Authority is required for regulated trials The Sponsorship responsibilities for Clinical Trials of Investigational Medicinal Products (CTIMPs) are governed by the EU Clinical Trial Regulation EU536/2014. The Sponsorship responsibilities for Clinical Investigation of a Medical Device are governed by the EU Medical Device Regulation 2017/745. For reference to current legislation please visit the HPRA website. Applicants are responsible for ensuring that all necessary approvals are in place prior to the start of the research.

10.2.1 Is regulatory approval from the HPRA required for this project? Y/N

10.3 Sponsorship

Please review the HRB Clinical Trials and Interventions Research Governance Policy[35]. Please note that all trials (Regulated and non-Regulated) directly funded by HRB are required to have a formal designated Sponsor (as defined in the policy). The Sponsor is responsible for delivering sponsorship oversight throughout the lifecycle of the study. *The HRB cannot act as the sponsor.* The sponsor for HRB-funded trials cannot be an individual or company.

Sponsorship oversight should be planned and put in place for the duration of the clinical trial. The level of oversight required during the implementation of the clinical trial should be assessed carefully and commensurate with the clinical trials risk level. All clinical trials and interventions must undergo a risk assessment (at the Host Institution level) before an application is submitted to support the sponsorship decision and oversight arrangements required[36]. **Lead Applicants should engage with their Host Institution as soon as they are invited to submit a Full Application to ensure sufficient time for this process.**

10.3.1 Please provide the name of the Clinical Trial Sponsor:

10.3.2 Please **upload a signed document**, on headed paper from the agreed sponsor. This **Letter of Sponsorship** must (a) confirm willingness to take on the role of the sponsor as defined in the HRB Clinical Trials and Interventions Research Governance Policy, and include details on (b) sponsor responsibilities for the study, (c) any responsibilities delegated to third parties and (d) confirming that the study will be conducted in compliance with Irish and European legislation and guidance and in accordance with the ethical and scientific principles of the Declaration of Helsinki and ICH guidelines.

11 Supporting Documentation

The following documents must be uploaded to complete the application

Mandatory documents:

- Objectives and Deliverables Gantt Chart

If applicable:

- Letter of Support for Lead Applicant or Co-Applicants in contract positions seeking their own salary
- Collaboration Agreement Form(s) - required for all collaborators
- Infrastructure Agreement Form(s) - required for access to Clinical Research Facilities and/or for biobanking

[35] https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-clinical-trials-and-interventions-governance/

[36] Many HRB Host Institutions contributed to the **Corporate Enabling of Clinical Research** initiative, which included work on common approaches to institutional risk assessments before taking on the role of clinical trial sponsor. For more information see the full 2019 report at https://ncto.ie/wp-content/uploads/2022/10/CECR-WEB.pdf, and contact your Host Institution in relation to their specific requirements

- Project Description Support file - A maximum of 5 figures which can be a combination of images, graphs, tables, scales, instruments, or surveys
- Participant Flow diagram (referred to in Section 5.10)

Submission of Applications

The deadlines for submission of complete applications are as follows:

- Submission deadline 1: Friday 25 April 2025 at 13:00. Funding decision expected Q4 2025.
- Submission deadline 2: Friday 18 July 2025 at 13:00. Funding decision expected Q1 2026.
- Submission deadline 3: Friday 17 October 2025 at 13:00. Funding decision expected Q2 2026.

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

Please note that the HRB will not follow up any supporting documentation related to the application, such as Host Institution's Letters of Support, Collaborator Agreement Form, Gantt charts etc. It is the responsibility of the Lead Applicant to upload all supporting documentation prior to submission. If the documentation is not received by the HRB on time, in the correct format or is not properly signed or submitted, the application will be deemed ineligible without further review.

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's Policy on Appeals on funding decisions is available at https://www.hrb.ie/wp-content/uploads/2024/09/HRB-Policy-on-Appeals-2.pdf

Appendix II: Checklist for Intervention studies

Regardless of whether your project involves an evaluation of a simple or a complex intervention and regardless of whether it is based on a randomised or a non-randomised design, the review Panels will take into account the following key questions when assessing the application. It is recommended that you use this checklist as a guide before finalising and submitting your application. It is also recommended that you seek advice from individuals or centres that are experts in study design and statistics before submitting your application.

The need for the study

- What is the problem to be addressed?
- What is/are the principal research question(s) to be addressed?
- Does your intervention have a coherent theoretical basis?
- Does the existing evidence – ideally collated from systematic reviews – suggest that it is likely to be effective or cost effective?
- What outcome are you aiming for and how might this bring about change?
- Can it be implemented in a research setting?
- Describe any risks to the safety of participants involved in the trial

The Proposed Study

- What is the proposed study design? e.g. randomised or non-randomised, experimental or observation design, pragmatic or equivalence, conventional parallel group RCT as opposed to cluster, factorial or stepped-wedge design etc.
- What are the planned interventions?
- Have you fully described 'usual care'?
- Indicate the number of subjects to be enrolled (both active treatment and controls)
- What are the proposed practical arrangements for allocating participants to study groups? E.g. Randomization method. If stratification or minimization are to be used, give reasons and factors to be included.
- What are the proposed methods for protecting against sources of bias? e.g. Blinding or masking. If blinding is not possible please explain why and give details of alternative methods proposed, or implications for interpretation of the trial's results
- How variable is the intervention (between sites, over time etc.)?
- Have you adequately described the context and the environment in which the evaluation is being undertaken?
- What are the planned inclusion/exclusion criteria?
- What is the proposed duration of intervention period?
- What is the proposed frequency and duration of follow up?
- Have you discussed reliability and validity of all study instruments or scales?
- What are the proposed primary and secondary outcome measures?
- How will the outcome measures be measured at follow up?

- Will health service research issues be addressed? Justify inclusion/exclusion of health economics and quality of life measures. If these measures are to be included full details should be given including power calculations.
- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include for both control and intervention groups, a brief description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate.
- It is important to give the justification for the size of the difference that the trial is powered to detect. Does the sample size calculation take into account the anticipated rates of non-compliance and loss to follow-up given below?
- What is the planned recruitment rate? How will the recruitment be organised? Over what time period will recruitment take place? What evidence is there that the planned recruitment rate is achievable?
- Are there likely to be any problems with compliance? On what evidence are the compliance figures based?
- What is the likely rate of loss to follow up? On what evidence is the loss to follow-up rate based?
- How many centres will be involved?
- Has any pilot or feasibility work been conducted to be confident that the intervention can be implemented as intended?
- Has acceptability testing been considered? What user involvement is there in the study?
- Is your study ethical?
- Are there any local or other contextual issues that need to be factored into the design?

Data Collection and Management

- What are the arrangements for day to day management of the trial? e.g. Randomisation, data handling, and who will be responsible for coordination?
- What arrangements have you put in place to oversee and monitor the evaluation?
- Is there a need for a trial steering Panel or a data safety and monitoring Panel?
- What is the proposed type of analyses?
- What is the proposed frequency of analyses?
- Are there any planned subgroup analyses?
- Will the design chosen really enable you to draw conclusions about effectiveness?

Appendix III: HRB Funding Policies and Procedures

Public and Patient Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public and patients in the research that we fund[37]. Public and patient involvement in research means that the public and patients are involved in planning and doing research from start to finish and help tell the public about the results of research. PPI, as defined here, is distinct from and additional to activities which raise awareness, share knowledge, and create a dialogue with the public, and it is also distinct from recruitment of patients/members of the public as participants in research.

PPI represents an active partnership between members of the public and patients and researchers in the research process. This can include, for example, involvement in the selection of research topics, assisting in the design, advising throughout or at specific decision points of 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.
- Help to ensure that the research uses outcomes that are important to the public.
- Identify a wider set of research topics than if health or social care professionals had worked alone.
- 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 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 https://hrbopenresearch.org/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.

In the application, you are asked to describe any public involvement in your research throughout the various stages of identifying and prioritising the research question, the research design, conduct, analysis, and dissemination. We recognise that the nature and extent of active public

[37] https://www.hrb.ie/funding/funding-schemes/public-and-patient-involvement-in-research/

involvement is likely to vary depending on the context of each study or award. PPI contributors should be named as Co-applicants where justified by their level of involvement.

For guidance and support on PPI in your research please consult with the PPI Ignite Network Ireland or your Host Institution. The PPI Ignite Network Ireland has offices located in the following seven Host Institutions: DCU, NUIG, RCSI, TCD, UCC, UCD, UL.

FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support open research[38] and open publishing directly through the HRB Open Research platform[39]. The HRB is driving the making of research data **FAIR** (**F**indable, **A**ccessible, **I**nteroperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles[40] provide a guideline for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals. For researchers, the move to FAIR and open data, where applicable, means researchers should consider data management issues and find suitable data repositories at the research planning stage. Applicants will have to provide information about their plans for data management and data sharing at application stage.

In line with the HRB's policy on management and sharing of research data[41], all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three months after the award start date, and a final updated version of the DMP with the last annual report.

The DMP will need to be submitted alongside a certification of completion from the designated representative(s) within the Host Institution.

Applicants will have to provide an outline of their plans for data management and data sharing in the application inclusive of the costs associated to the plan.

The timing for completion and submission of the DMPs must be also included among the objectives and deliverables of the programme.

General Data Protection Regulation

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

[38] https://www.hrb.ie/wp-content/uploads/2024/10/Open-Access-to-research-publications.pdf

[39] https://hrbopenresearch.org/

[40] https://www.nature.com/articles/sdata201618

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

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

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

The Health Research Regulations (HRR)

Following the implementation of GDPR, a regulation for health research known as the Health Research Regulations 2018 (S.I. 314) has been implemented, with further amendments made in 2019 (S.I. 188) and 2021 (S.I. 18)[42]. These regulations outline the mandatory suitable and specific measures for the processing of personal data for the purposes of health research. They further set out that explicit consent is a mandatory safeguard that must be obtained from individuals when using their personal data for health research. Where it is not feasible to obtain explicit consent, an application for a consent declaration can be made to the Health Research Consent Declaration Committee[43].

Research on Research

The HRB is developing its approach to research on research (RoR) with the aim of enhancing the evidence base for HRB research funding practices. We may also collaborate with researchers on request regarding specific RoR questions. Should your application become of interest to such a study, the HRB will seek your consent for the use of your information.

[42] http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

[43] https://hrcdc.ie/

HRB Gender Policy

In line with international best practice, the **HRB Gender Policy**[44] recognises the responsibility of the HRB to support everyone 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. 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.

Conflict of Interest

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

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

Appeals Procedure

The HRB's Policy on Appeals on funding decisions is available at https://www.hrb.ie/wp-content/uploads/2024/09/HRB-Policy-on-Appeals-2.pdf.

Privacy Policy

To understand why we collect the information we collect and what we do with that information, please see our Privacy Policy[45]

[44] https://www.hrb.ie/wp-content/uploads/2024/05/HRB-Policy-on-Gender-in-Research-Funding-2.pdf

[45] https://www.hrb.ie/privacy-notice/

Appendix IV: Resource and Useful Links

Clinical Trials Infrastructures

Clinical Research Facilities/Centres (CRF/Cs). These are located in hospital sites and provide the space, facilities, governance, services, supports, and the skills and expertise to enable high-quality, safe and compliant trials.

- **Wellcome Trust-HRB Clinical Research Facility, St James's Hospital (WT-HRB CRF SJH)**
  http://www.sjhcrf.ie/
- **Clinical Research Facility, University College Dublin (UCD CRC)**
  https://www.ucd.ie/medicine/research/ucdclinicalresearchcentre/
- **Clinical Research Centre, Royal College of Surgeons in Ireland (RCSI CRC)**
  https://www.rcsi.com/clinical-research-centre
- **Children's Health Ireland Clinical Research Centre (CHI CRC)**
  https://www.childrenshealthireland.ie/research-innovation-index/research-at-chi/
- **HRB Clinical Research Facility, Cork (HRB CRFC)**
  https://crf.ucc.ie/
- **HRB Clinical Research Facility, Galway (HRB CRFG)**
  http://www.nuigalway.ie/hrb_crfg/
- **Health Research Institute Clinical Research Support Unit, Limerick**
  https://www.ul.ie/hri/clinical-research-support-unit
- **UCD Clinical Trials Unit (UCD CTU)**
  https://www.ucd.ie/medicine/ctu/
- **Institute for Clinical Trials, University of Galway**
  https://www.universityofgalway.ie/instituteforclinicaltrials/

Clinical Trial Networks (CTNs). These are groups of researchers that have come together to identity important clinical questions and design clinical trials to answer them.

- **Irish Critical Care Clinical Trials Network (ICC CTN)**
  https://iccctn.org/
- **Irish Network for Children's Clinical Trials (in4kids)**
  https://in4kids.ie/
- **HRB Primary Care Clinical Trial Network Ireland**
  https://primarycaretrials.ie/
- **HRB Diabetes Collaborative Clinical Trial Network (DC CTN)**
  https://diabetestrialsctn.ie/
- **Infectious Diseases Clinical Trials Network Ireland (ID CTNI)**
  https://www.ucd.ie/medicine/research/idctni/

- **Rare Disease Clinical Trial Network (RD CTN)**
  https://rarediseaseresearch.ie/
- **Dementia Trials Ireland (DTI)**
  https://dementiatrials.ie/
- **Cancer Trials Ireland (CTI)**
  https://www.cancertrials.ie/

Cancer Trial Groups. These are cancer trial delivery units aligned to existing clinical trials infrastructures, hospital groups and academic institutions.

- **CHI Cancer Trials Group**
  https://www.childrenshealthireland.ie/research-innovation-index/research-at-chi/
- **RCSI Cancer Trials Group**
  https://beaumontrcsicancercentre.ie/
- **UCC Cancer Trials Group**
  https://ucccancertrials.ie/
- **Ireland East Hospital Group (IEHG) Cancer Trials Group**
  https://stvincentsucdcancercentre.ie/research/
- **Trinity Academic Cancer Trials Group**
  https://www.stjames.ie/cancer/
- **Saolta Cancer Trials Group**
  https:www.saolta.ie/cancer-centre/clinical-trials
- **Irish Research Radiation Cancer Trials Group (IRROG)**
- **Limerick Cancer Trials Group**

Study Design & Methodology for Clinical Trials and Intervention Studies

Methodology

- **HRB Trials Methodology Research Network (TMRN).** The HRB TMRN provide trials methodology research and training supports.
  http://www.hrb-tmrn.ie
- **The Northern Ireland Hub for Trials Methodology Research**
  https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/
- **SWAT Repostitory Store.** This is a central platform for planned or ongoing SWAT/SWAR studies.
  https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodology/SWATStore/
- **Trial Forge.** Trial Forge aims to increase the quantity and quality of trial methodology research.
  https://www.trialforge.org/
- **NIHR-INCLUDE Framework.** Guidance on improving inclusion of under-served groups in research.
  https://www.nihr.ac.uk/INCLUDE

Study Design

- **"Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework"** by Eldridge S. *et al.* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0150205
- **"Pilot and feasibility studies: extending the conceptual framework"** by Eldridge S. *et al.* https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-023-01233-1
- **PRECIS-2.** Pragmatic Explanatory Continuum Indicator Summary (PRECIS) is a tool to help trialists design clinical trials that are fit for purpose. https://www.precis-2.org/
- **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/
- **SPIRIT 2013 Statement.** Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) is a guideline for the minimum content of a clinical trial protocol. It is widely endorsed as an international standard for trial protocols. https://www.acpjournals.org/doi/10.7326/0003-4819-158-3-201302050-00583
- **SPIRIT 2024 Update** is under development, see the consort-spirit.org website
- **"Developing and Evaluating Complex Interventions"** by MRC, UK https://www.bmj.com/content/337/bmj.a1655
- **"A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance"** by MRC, UK BMJ 2021; 374 :n2061 doi:10.1136/bmj.n2061
- **"Process evaluation of complex interventions: Medical Research Council guidance"** by MRC, UK https://www.bmj.com/content/350/bmj.h1258
- **"Using natural experiments to evaluate population health interventions: Guidance for producers and users of research evidence"** by MRC, UK https://pubmed.ncbi.nlm.nih.gov/22577181/
- **HIQA Guidelines** for the Economic Evaluation of Health Technologies in Ireland (2018) https://www.hiqa.ie/reports-and-publications/guidelines-economic-evaluation-health
- **HIQA Guidelines** for the budget Impact Analysis of Health Technologies in Ireland (2015) https://www.hiqa.ie/reports-and-publications/guidance-budget-impact-analysis
- **HIQA Guidelines** for Evaluating the Clinical Effectiveness of Health technologies in Ireland (2011) https://www.hiqa.ie/sites/2019-01/Clinical-Effectiveness-Guidelines.pdf

Ethical and Regulatory Approvals and Oversight

- **HSE National Framework for the Governance, Management and Support of Health Research** (RGMS Framework) https://hseresearch.ie/HSE-Framework.pdf

- **HSE Research and Development Resources**
  Research ethics https://hseresearch.ie/research-ethics/
  Consent in health and social care research https://hseresearch.ie/consent/
  Clinical trials https://hseresearch.ie/clinical-trials/
- **National Office for Research Ethics Committees (NREC).** NREC is responsible for providing a single REC opinion for clinical trials of medicinal products and investigations of medical devices**.** https://www.nrecoffice.ie/
- **Health Research Consent Declaration Committee (HRCDC).** The HRCDC was established as part of the Health Research Regulations in 2018. A consent declaration may be needed in occasional circumstances only.
  https://hrcdc.ie/
- **Health Products Regulatory Authority (HPRA).** The national competent authority in Ireland. https://www.hpra.ie/
- **Clinical Trials Information System (CTIS).** All regulated clinical trials that come under the EU Clinical Trial Regulation (CTR) must be submitted as a single combined application using CTIS. https://euclinicaltrials.eu/
- **European Clinical Research Infrastructure Network (ECRIN) Regulatory and Ethical Database (RED).** ECRIN RED is a central resource for clinical trial ethical and regulatory requirements covering a number of European countries, including Ireland.
  https://red.ecrin.org/en
- **ICH Guidelines for Good Clinical Practice (GCP).** The updated ICH GCP E6(R3) guidelines were adopted on 06 January 2025.
  https://database.ich.org/ICHE6FinalGuideline.pdf

Clinical Trial Registration

- **All Trials Initiative**
  http://www.alltrials.net/
- **International Clinical Trials Registration Platform** (run by the WHO)
  http://apps.who.int/trialsearch/Default.aspx
- **US National Library of Medicine database:** database of privately and publicly funded clinical studies conducted around the world
  https://www.clinicaltrials.gov/
- **ISRCTN Registry**
  https://www.isrctn.com/
- **EU Clinical Trials Register** (EudraCT): database of all regulated clinical trials which commenced in the EU from 01 May 2004 https://eudract.ema.europa.eu/. **From 31 January 2025, all regulated clinical trials of medicinal products fall under the EU CTR and applications must be submitted via CTIS.**
- **CTIS** https://euclinicaltrials.eu/

Clinical Trial Reporting

- **Consort 2010 Statement.** Consolidated Standards Of Report Trials (CONSORT) is a guideline for reporting randomised clinical trials completely and transparently. It is widely endorsed as an international standard for reporting of clinical trials.
  https://www.bmj.com/content/340/bmj.c332
- **Consort 2024 Update** is under development, see the consort-spirit.org website
- **TIDieR.** Template for intervention description and replication (TIDieR) is a checklist and guide to improve the quality of reporting and the replicability of interventions.
  https://www.bmj.com/content/348/bmj.g1687
- **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/
- **SQUIRE 2.0.** Standards for Quality Improvement Reporting Excellence (SQUIRE).
  https://www.equator-network.org/reporting-guidelines/squire/

Logic Models

- **NIHR**: Creating a logic model for an intervention: evaluation in health and wellbeing
- **University of Wisconsin Madison:** https://logicmodel.extension.wisc.edu/

Public and Patient Involvement in research and research priorities

- **The National PPI Ignite Network.** The PPI Ignite Network promotes excellence and inspires innovation in PPI in health and social care in Ireland**.**
  https://ppinetwork.ie/
- **HSE Research and Development PPI Resources**
  https://hseresearch.ie/patient-and-public-involvement-in-research/
- **NIHR PPI resources**
  https://www.nihr.ac.uk/application-support/working-with-people-and-communities

  Resources and training for public involvement in health and social care research
  https://www.learningforinvolvement.org.uk/

  How to involve the public in knowledge mobilisation
  https://evidence.nihr.ac.uk/collection/how-to-involve-the-public-in-knowledge-mobilisation/

  Payment guidance for researchers and professionals
  https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/
- **Patient-Centred Outcomes Research Institute (PCORI)**
  http://www.pcori.org

- **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/
- **European Patient Forum Value and Handbook:**
  http://www.eu-patient.eu/globalassets/projects/valueplus/doc_epf_handbook.pdf
- **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/
- **Campus Engage:** Supporting Irish HEIs to embed civic engagement in their work. Includes resources, how-to-guides, and case studies for engaged research.
  http://www.campusengage.ie/what-we-do/publications/
- **UK Standards for Public Involvement:** The six UK Standards for Public Involvement provide clear, concise statements of effective public involvement against which improvement can be assessed.
  https://sites.google.com/nihr.ac.uk/pi-standards/home
- **The Involvement Matrix:** A tool for researchers to promote collaboration with patients in research.
  https://www.kcrutrecht.nl/involvement-matrix/
- **The Evaluation Toolkit:** A resource designed for practitioners of the health sector, produced after the completion of a systematic review of patient and public engagement evaluation tools.
  https://ceppp.ca/en/evaluation-toolkit/
- **GRIPP2 Checklists:** Tools to improve reporting of patient and public involvement in research.
  https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-017-0062-2#Tab

Evidence Synthesis

- **Evidence Synthesis Ireland**. ESI aims to build evidence synthesis knowledge, awareness and capacity among the public, health care institutions and policymakers, clinicians, and researchers in Ireland.
  https://evidencesynthesisireland.ie/
- **The Cochrane Library.** An online collection of databases in medicine and other healthcare specialties which summarise and interpret the results of medical research.
  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.
  The Campbell Collaboration: https://www.campbellcollaboration.org/
  The UK & Ireland Hub: https://www.qub.ac.uk/research-centres/CampbellUKIreland/

Gender and/or sex issues in research

- **Examples of case studies in Health & Medicine where gender/sex in research matters**
  http://genderedinnovations.stanford.edu/case-studies-medicine.html
- **Gender Toolkit in EU-funded research for examples and guidance**
  http://www.yellowwindow.be/genderinresearch/GenderToolKit.pdf
- **Sex/Gender Influences in Health and Disease**
  https://orwh.od.nih.gov/sex-gender/orwh-mission-area-sex-gender-in-research
- **Methods and Techniques for Integrating Sex into Research**
  https://orwh.od.nih.gov/sex-gender/methods-techniques-integrating-sex-research
- **NIH Policy on Sex as a Biological Variable**
  https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable

Inclusion of underserved groups in research

- **NIHR-INCLUDE Framework.** Innovations in Clinical Trial Design and Delivery for the under-served (INCLUDE) provides guidance on improving inclusion of under-served groups in clinical research.
  https://www.nihr.ac.uk/INCLUDE
- **Statement by the National Athena SWAN Ireland Intersectionality Working Group** on the Use of Ethnicity Categories in Irish Higher Education
  Intersectionality-WG-Statement-on-Ethnicity-Categories-in-Irish-HE.pdf (hea.ie)

Knowledge translation resources

- **HSE Research & Development Knowledge translation resources**
  https://hseresearch.ie/research-dissemination-and-translation/
- **HSE Research and Development: Dissemination, Knowledge Translation and Impact**
  https://hseresearch.ie/research-dissemination-and-translation/
- **Integrated Knowledge Translation (iKT) NUI Galway**
  https://www.nuigalway.ie/hbcrg/ikt/
- **The Canadian Institutes of Health Research:** Guide to Knowledge Translation Planning
  https://cihr-irsc.gc.ca/e/45321.html
- **Training Institute for Dissemination and Implementation Research in Health:** Open Access Course
  https://cancercontrol.cancer.gov/is/training-education/TIDIRC-open-access

Implementation science resources

- **Centre for Effective Services**
  https://www.effectiveservices.org/resources/implementation

- **UCC Implementation Science Training Institute**
  https://www.ucc.ie/en/cpd/options/medhealth/cpd1778uccimplementationsciencetraininginstitute/
- **European Implementation Collaborative**
  https://implementation.eu/resources/

Co-creation resources

- **ACCOMPLISSH Guide to impact planning**
  https://www.ugent.be/psync/en/what/projects/impactplanning.pdf
- **Working together to co-create knowledge: A unique co-creation tool – Carnegie UK Trust**
  https://www.carnegieuktrust.org.uk/publications/working-together-to-co-create-knowledge-a-unique-co-creation-tool/

Biobanking

- **Council of Europe Recommendation of the Committee of Ministers to member States on research on biological materials of human origin (2016)**
  https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff
- **BBMRI-ERIC.** BBMRI-ERIC is a European research infrastructure for biobanking.
  https://www.bbmri-eric.eu/
- **OECD Guidelines on Human Biobanks and Genetic Research Databases**
  https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0375
- **ISBER Best Practices for Repositories**
  https://www.isber.org/page/BPR
- **Molecular Medicine Ireland Biobanking Guidelines**
  https://www.liebertpub.com/doi/10.1089/bio.2010.8101
- **NCI Best Practices for Biospecimen Resources (2016 version)**
  https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf

Data management and sharing and Fair Principles

- **Digital Curation Centre:** How to develop a data management and sharing plan (with examples)
  http://www.dcc.ac.uk/resources/data-management-plans/guidance-examples
- **FAIR data principles FORCE 11**
  https://www.force11.org/fairprinciples
- **UK Concordat on Open Research Data (July 2016)**
  https://www.ukri.org/ConcordatonOpenResearchData.pdf
- **Guidelines on FAIR data management plans in Horizon 2020**
  http://ec.europa.eu/research/participants/data.pdf

- **FAIR at the Dutch centre for Life sciences**
  https://www.dtls.nl/fair-data/

Research Data Management Plans

- **Data Stewardship Wizard created by ELIXIR CZ and NL**
  https://ds-wizard.org/
- **DMPonline of the Digital Curation Centre (DCC), UK**
  https://dmponline.dcc.ac.uk/
- **DMPTool of University of California Curation Center of the California Digital Library (CDL), USA**
  https://dmptool.org/
- **RDMO Research Data Management Organiser of the German Research Foundation, Germany**
  https://rdmorganiser.github.io/en/

Information on persistent identifiers

- **DOI:** List of current DOI registration agencies provided by the International DOI Foundation
  http://www.doi.org/registration_agencies.html
- **Handle:** Assigning, managing and resolving persistent identifiers for digital objects and other Internet resources provided by the Corporation for National Research Initiatives (CNRI)
  http://www.handle.net/
- **URN:** List of all registered namespaces provided by the Internet Assigned Numbers Authority (IANA)
  https://www.iana.org/assignments/urn-namespaces/urn-namespaces.xml

Data repositories

- **Registry of Research Data Repositories**
  http://www.re3data.org/
- **Data centers accredited by the German Data forum according to uniform and transparent standards (Germany)**
  https://www.konsortswd.de/ueber-uns/ratswd/
- **Zenodo Data Repository (OpenAIR)**
  https://zenodo.org/