# HRB Primary Care Clinical Trials Network Pre-Application Supports Request Form

# Health Research Board

# Investigator-Led Clinical Trials (ILCT) Programme 2025 (previously DIFA)

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# 1. Submitting a support request

Lead Investigators planning an application to the HRB ILCT 2025 scheme who wish to request supports from the HRB Primary Care CTNI should complete this form and return to [**primarycaretrials@universityofgalway.ie**](mailto:primarycaretrials@universityofgalway.ie)**.**

A description of any supports agreed between the Lead Investigator and the HRB Primary Care CTNI will be included in **Section 5. Infrastructure and Support** of the HRB GEMS form. We aim to finalise agreements on supports in a timely manner, but encourage all potential applicants seeking support to engage with us as early as possible.

## 1.1 Key Dates

The ILCT is a rolling call, with 3 funding decisions expected in 2025/26:

* Applications submitted before **25 April 2025** will be reviewed in the first cycle, outcomes are expected in **November 2025**. The anticipated earliest start date for these grants is **01 February 2026**.
* Applications submitted before **18 July 2025** will be reviewed in the second cycle, outcomes are expected in **February 2026**. The anticipated earliest start date for these grants is **01 May 2026**.
* Applications submitted by **17 October 2025** will be reviewed in the final cycle, outcomes are expected in **May 2026**. The anticipated earliest start date for these grants is **01 August 2026**.

The CTNI will accept support requests up to 12 working days before the close of each cycle. We will endeavour to keep to the following timeline for each request, subject to the exact supports requested and all necessary information being provided by the Lead Investigator.

PLEASE NOTE: The HRB Primary Care CTNI is funded by the HRB through November 2026. Any supports we offer can only be guaranteed up to that date. We will acknowledge this in any infrastructure agreements we provide.

## 1.2 Review timeline

We aim to have submitted forms reviewed internally for suitability, and any additional information requested, within 3 working days of receipt of form.

Draft wording of an infrastructure agreement will be provided within 5 working days.

A meeting will be arranged within 10 working days between the applicant team and the CTNI to discuss the wording of the infrastructure agreement.

Finalised wording of the infrastructure agreement will then be provided to the applicant team within 11 working days.

# 2. About the HRB Primary Care CTNI

The HRB Primary Care CTNI was established in 2015 as a collaborative partnership between NUI Galway, the Royal College of Surgeons in Ireland, Queen’s University Belfast, the Association of University Departments of General Practice in Ireland, and the Irish College of General Practitioners. Since establishment, it has supported more than 30 clinical studies, recruited almost 4,000 patients, leveraged funds of over €19,000,000, and published in leading international journals such as the New England Journal of Medicine, the Lancet, and the British Medical Journal.

In 2021, the HRB Primary Care CTNI was successful in securing funding for the next 5 years of operations, with a focus on achieving the following strategic objectives:

1. To maximise the successful delivery of primary care trials in Ireland.
2. To continue to build capacity for world-class clinical trials in Irish primary care, through the provision of financial supports to early career researchers, the promotion of primary care research education and dissemination, and the provision of seed funding to develop a roadmap for implementation of a national research IT infrastructure.
3. To develop an agenda for Irish primary care clinical trials research, centred around the [Top Ten Research Priorities for the management of chronic conditions in primary care](https://primarycaretrials.ie/psp/).
4. To enhance patient and public involvement (PPI) in primary care research in Ireland, by continuing to grow the capacity of the Primary Care CTNI PPI group, including PPI in network oversight and portfolio development, and continuing our synergistic relationship with the national PPI network.

## 2.1 The Core Operations Team

**Network Director:** Professor Andrew W. Murphy

**Associate Director**: Professor Susan Smith

**Acting Network Manager/Research Lead**: Ms Laura O’Connor

**Network Administrator**: Ms Breda Kelleher

For more about the Core Operations Team, visit: <https://primarycaretrials.ie/about-us/core-team/>

# 3. ILCT Call

The Investigator-Led Clinical Trials (ILCT) Programme 2025 is the new name for the Definitive Interventions and Feasibility Awards (DIFA) scheme administered by the HRB. The scope, aim and objectives remain the same, however there are changes Lead Investigators must be aware of. Full details of the scheme can be found on the HRB website, with some key changes highlighted below (<https://www.hrb.ie/funding-scheme/investigator-led-clinical-trials-ilct-programme-2025/>)

* Unlike the last DIFA call, the ILCT 2025 call is a one-stage submission process.
  + If unsuccessful in the first cycle, one resubmission, with a revised application in line with reviewer feedback, may be submitted to a later cycle.
  + As an open call, applicants may begin an application on GEMS and submit at any point while the call is open, and it will be reviewed in the currently open cycle at time of submission.
* There are 2 separate streams for a Definitive Intervention, and a Feasibility Study. Applicants will need to confirm on GEMS which stream they are applying to.
* There is no Co-Lead Applicant option in the ILCT 2025 call.
* Maximum budgets are €1,300,000 for a Definitive Intervention, and €430,000 for a Feasibility Study, both inclusive of overheads. The budget for a methodology sub-study (including a SWAT) remains at €20,000 inclusive of overheads
* €3M of the overall ILCT budget will be aimed at supporting cancer-specific trials, quality of applications permitting.

# Your ILCT Application Overview

Please complete this form using **current best estimates**. We understand this information may change during the application process.

|  |  |
| --- | --- |
| **Application Title** |  |
| **Lead Applicant** |  |
| **Host Institution** |  |
| **Targeted cycle deadline (25 April, 18 July, or 17 October)** |  |
| **Duration, and anticipated start and finish dates** |  |
| **Study Type (Definitive Trial, Feasibility Study, with/without SWAT)** |  |
| **Estimated Budget Total** |  |
| **Draft Abstract (maximum 500 words)** | |
|  | |

# The Role of the HRB Primary Care CTNI

Sections 5 and 6 of this form focus on specifying the nature of supports being requested from the HRB Primary Care CTNI. Depending on the nature and extent of the requested supports, it may be appropriate for a member of the Core Operations Team to be named as a co-applicant or collaborator in the application. See section 5.1.2 of the [ILCT Programme Guidance Notes](https://www.hrb.ie/wp-content/uploads/2025/02/ILCT-Programme-2025-FS-Stream-Guidance-Notes.pdf) for full information on these roles.

In summary, a co-applicant has a well-defined, critical and substantial role in the conduct and steering of the proposed research. A co-applicant may receive funding for items such as running costs and personnel, and can request their own salary or proportion of their salary, depending on their role and percentage of time dedicated to the research project. An official collaborator is an individual or an organisation that provides an integral and discrete contribution (either direct or indirect) to the proposed research activities.

|  |  |
| --- | --- |
| **What role is envisaged for the HRB Primary Care CTNI in this application?** | Infrastructure Agreement Only [ ]  Collaborator [ ]  Co-applicant [ ] |
| **Please justify the role envisaged.** |  |

# Practice and Patient Recruitment Supports

If you wish to recruit practices through the HRB Primary Care CTNI, please complete the tables below using **current best estimates**. We understand this information may change during the application process. Not all sections may be relevant to all applications.

|  |  |
| --- | --- |
| **Target number of practices** |  |
| **Practice inclusion criteria** |  |
| **Practice exclusion criteria** |  |
| **What does the study require practice staff to do?** |  |
| **Target patient recruitment (total)** |  |
| **Target patient recruitment per practice (if applicable)** |  |
| **Financial and other supports to practices** |  |
| **When will practice recruitment begin?** |  |

|  |  |
| --- | --- |
| **Have inclusion and exclusion criteria for patients been defined?** | Yes [ ] No [ ] |
| If yes, please specify: | |

# Other Supports Requested

Please indicate which of the following additional supports are being requested, using **current best estimates**. We understand this information may change during the application process.

|  |  |
| --- | --- |
| **Methodology Advice (including protocol development, intervention develop, health behaviour change, health economics, and implementation science.)** | Yes [ ] No [ ] |
| If yes, please specify: | |
| **Patient and Public Involvement (PPI)** | Yes [ ] No [ ] |
| If yes, please specify: | |
| **Ethical Approvals Guidance, Data Protection, and FAIR Data Management and Stewardship** | Yes [ ] No [ ] |
| If yes, please specify: | |
| **Regulatory Guidance** | Yes [ ] No [ ] |
| If yes, please specify: | |
| **Dissemination Supports** | Yes [ ] No [ ] |
| If yes, please specify: | |
| **Other** | Yes [ ] No [ ] |
| If yes, please specify: | |

# Budgeting

Depending on the level of support requested, you may need to make provision in your budget for the support you are requesting.

We will discuss with you how best to support your research either within the current resources of the CTN or with additional resources from your budget. Please account for each requested support in the table below, providing estimates where possible.

Please use the table below to show how the requested supports will be budgeted for.

|  |  |  |
| --- | --- | --- |
| Category of Support | Specify if supports are requested as 1,2 or 3   1. In-kind Contribution 2. Funding included in project budget 3. Funding included in another budget | For 2 and 3, specify the budgeted amount. |
| e.g., practice recruitment |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

# Research Priorities

The HRB Primary Care CTNI have led on the development of the [Top Ten Research Priorities for the management of chronic conditions in primary care](https://primarycaretrials.ie/psp/), with the support of the [James Lind Alliance](https://www.jla.nihr.ac.uk/top-10-priorities).

If your application aligns with any of these priorities, please mark the box(es) below and give a brief description of how your proposal may provide relevant information for answering this question.

|  |  |  |
| --- | --- | --- |
| **#** | **Research Priority** | **Mark if relevant** |
| 1 | How can exchange of information be improved between specialist/hospital services and primary care for both people with chronic conditions and healthcare professionals? |  |
| 2 | What non-drug treatments for managing chronic conditions (e.g., exercise and other lifestyle changes, physical therapies, talk therapies) could be integrated into primary care services instead of or in addition to medications? |  |
| 3 | How can a multidisciplinary approach (e.g. the involvement of a mix of health care professionals) be implemented when managing chronic conditions in primary care? |  |
| 4 | How can primary health care data be used to inform chronic condition management, both in the care of individual patients and in the delivery of services more broadly? |  |
| 5 | In what ways can primary care understand and address patient and family/carer treatment burden, i.e., the work people have to do to manage chronic conditions and the impact that has? |  |
| 6 | What is the best way to ensure appropriate and timely access to Irish primary care services for people managing chronic conditions? |  |
| 7 | How can primary care services best manage the complexities of caring for people with multiple chronic conditions (across the lifespan)? |  |
| 8 | How can people with chronic conditions be best supported to engage with and navigate health and social care information and services? |  |
| 9 | What is the best way to support continuity of care for people with chronic conditions within primary care, including continuity in their relationships with primary care professionals and in the management and coordination of their care? |  |
| 10 | How can primary care services support good mental health and wellbeing for people managing chronic conditions and symptoms? |  |
| **Brief description** | | |
|  | | |