Investigator-led Clinical Trials Programme (ILCT) 2025

Frequently Asked Questions

1. General

Is this a new scheme?

The HRB Investigator-led Clinical Trials Programme (ILCT) 2025 is **not** a new scheme. It was formerly known as the HRB Definitive Interventions and Feasibility Awards (DIFA) scheme. The scope, aims and objectives remain unchanged. The structure of the call has been revised to provide a more flexible funding mechanism and to shorten timelines to fund investigator-led clinical trials in Ireland.

Will there be an information webinar on ILCT Programme 2025?

Yes. The HRB will host an information webinar on **Thursday 27 February 2025 at 11am** to give an overview of the ILCT Programme. We encourage all interested applicants, Clinical Research Facility and Research Office staff to attend. The registration link will be made available on the HRB website.

What are the changes to the ILCT Programme 2025?

Submission process:

- ILCT 2025 has moved to a **one-stage submission** process. No pre-submission applications are required. Instead, applicants should submit one full application.
- There are **two separate submission streams** as part of the ILCT Programme 2025. Applicants wishing to apply for a definitive intervention study should apply via the Definitive Intervention stream, while those wishing to apply for a smaller feasibility study should apply via the Feasibility Study stream on GEMs. You will be asked to confirm on GEMs that you are applying for the right study type.
- ILCT 2025 is now structured as an **open rolling call,** with pre-agreed application submission deadlines after which the review process will commence. This means that applicants can work up an application on GEMs and submit it at any time from the call launch (05 February 2025) up until 17 October 2025 when the call closes.
    - Applications submitted before **25 April 2025** will be reviewed in the first cycle and 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 and 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 and outcomes are expected in **May 2026**. The anticipated earliest start date for these grants is **01 August 2026.**

    Please note, if you miss any of the above submission deadlines, your application will be reviewed in the next review cycle.
- If your application is reviewed and not recommended for funding in the first cycle, you may resubmit your application at the next appropriate submission deadline. However, you will need

to demonstrate that you have taken reviewer feedback on board and revised your application accordingly. **Only one resubmission is allowed per application.**

Co-Lead Applicant Option:

The Co-lead Applicant option has been removed from the ILCT Programme 2025. Instead, the applicant team should include an appropriate Lead Applicant and up to 15 Co-Applicants (Research Co-Applicants and/or PPI Co-Applicants) and Collaborators.

Budget:

The maximum available budget has increased to €1,300,000 inclusive of overheads for definitive intervention studies, and to €430,000 inclusive of overheads for feasibility studies. The budget for a methodology sub-study (including a SWAT) remains at €20,000 inclusive of overheads.

How do I apply for a definitive intervention or feasibility study via ILCT Programme 2025?

All applications must be made using the HRB online Grant E-Management System GEMS. Applicants are strongly advised to carefully read the Guidance Notes prior to application and ensure they are applying to the **appropriate funding stream** on GEMS.

The Lead Applicant must create the application, but it can then be jointly completed by the named Co-Applicants. Once the Lead Applicant starts the application s/he will be asked to go through a check list of mandatory Yes/No questions prior to completing the form. In order to continue with the application the Lead Applicant must satisfy the conditions of this check list.

What is the submission process using GEMS?

Prior to final submission to the HRB, all applications must first be reviewed and approved within GEMS by the signatory approver at the research office (or equivalent) at the Host Institution. It is critical therefore that Lead 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.

What is the closing date for submission of applications?

As this is structured as an opening rolling call, applications can be submitted via GEMs any time from 04 February 2025 to 17 October 2025 for consideration in one of the three review and decision cycles indicated above.

2. Scope of ILCT Programme 2025

Is it permitted to join an international collaboration and operate as the Irish arm of the collaborative study?

Yes, provided the relevant sections are filled out in the application form and the original protocol for the study is provided with your full application.

Are per-patient costs for international studies eligible costs in ILCT Programme 2025?

Costs associated with trial activities outside the island of Ireland are not eligible costs for the ILCT programme. 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. For international trials where Ireland is coordinating or sponsoring the trial,

costs relating to sponsorship/trial coordination can be included (including insurance/indemnity, monitoring, shipping, statistical support, FAIR data management etc).

Is it possible to set up collaborations with international sites?

Yes, it is permitted to set up projects with international collaborators. Sufficient justification should be provided to explain why an international collaborator was chosen instead of a national one. It will be important to stress the benefits to the Irish health system of using international collaborators.

Can researchers from Northern Ireland participate?

Applicants from Host Institutions in Northern Ireland cannot apply as Lead Applicant, but they can apply as a Co-Applicant/Collaborator and receive funding if fully justified.

Can I undertake translational research using samples taken as part of my clinical trial?

No, translational research is not within scope of this call. However, collection of additional samples for storage and later translational work is permitted and the associated costs for this collection and storage may be claimed where appropriately described and justified.

Can funding be requested for a methodology sub-study?

An additional €20,000 (inclusive of overheads) can be applied for if conducting a methodology sub-study, including a SWAT. Please note that individual proposed studies may cost more or less than €20,000 therefore actual costs should be included.

3. Lead Applicant

Can a Lead Applicant submit more than one application?

No, only one application per Lead Applicant will be considered in this round. However, the Lead Applicants can be a Co-Applicant or Collaborator in another application provided they have the time commitment to fulfil both roles, should the applications be successful.

Please also note, a Lead Applicant can only submit for a definitive intervention (via the DI stream) or a feasibility study (via the FS stream). **Lead applicants cannot submit to both streams of the ILCT Programme.**

Can a contract researcher be a Lead Applicant and apply for their own salary?

Yes, a contract researcher acting as Lead Applicant can apply for their salary. A Host Institution Letter of Support is required at full application stage for all contract researchers acting as Lead Applicant.

Can I be Lead Applicant on one application and Co-Applicant on another?

Yes, it is worth bearing in mind however that should both applications reach review Panel stage the amount of time you are spending on both will be scrutinised so this should be realistic.

4. Co-Applicants and Collaborators

How many Co-Applicants and Collaborators can I have?

The ILCT Programme 2025 round will allow up to a **maximum of 15 co-applicants and collaborators in total.**

Can a Co-Applicant receive payment for their role in the project?

Co-Applicants who are contract researchers may receive a salary. A Host Institution Letter of Support is required for co-applicants who are contract researchers and are applying for their own salary. Please note the HRB does not fund the salary and related costs of academic staff within research institutions (including buy out from teaching time etc.)

A Co-Applicant may also receive funding for items such as running costs and personnel.

Does a Co-Applicant's contract have to cover the duration of the award?

There are no requirements for the duration of a Co-Applicant's contract. However, where a Co-Applicant is applying for salary, their contract must cover the duration of the award or the Host Institution must be willing to issue/extend a contract should the award be successful; this should be contained in the Co-Applicants letter of support.

How many Co-Applicants and Collaborators can I have?

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.**

We would not anticipate more than **10 Co-Applicants** to be included (up to a **maximum of 15 co-applicants and collaborators in total**).

Do Co-Applicants need to have support letters?

Host Institution letters of support are only required where Co-Applicants are contract researchers applying for their own salary.

Can a Co-applicant/Collaborator be from outside Ireland?

Yes, Co-applicants/Collaborators from outside Ireland are welcome where the nature of the research renders this necessary and is appropriately justified.

Will the HRB pay for visits from or to Co-applicants/Collaborators?

Yes, visits to or from Co-Applicants/Collaborators where justified may be included under running costs.

Is a Collaborator agreement form needed?

A Collaborator agreement form must be signed by each Collaborator and uploaded with your application.

Can a Collaborator be from private enterprise?

Yes, a collaborator may be from private enterprise. Applications from a private enterprise are encouraged where they add value to the project for example in terms of access to expertise, technologies or reagents. The HRB does not have the capacity to broker these arrangements. The terms of the collaboration should be determined early, and relevant agreements must be in place by the onset of the project. Consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples.

Can a Collaborator receive payment for their role in the project?

Yes, collaborators are eligible to receive funding from the award when properly detailed and justified in the application.

What is Public, Patient and Carer Involvement (PPI)?

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

Will PPI play a large role in this grant call?

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. Depending on the role in delivering the research activities, PPI contributors can be included as Co-Applicants or Collaborators.

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

5. Supporting documents

What documents should be uploaded with my application form?

You must upload the following documents:

- Host Institution Letters of Support, if applicable
- Collaborator agreement forms, if applicable
- Infrastructure Agreement Forms, if applicable
- Letter of Sponsor
- Objectives and Deliverables Gantt chart
- Participant flow diagram
- Logic model (optional)
- For International Studies, a copy of the full Protocol
- Project Description Figures: A maximum of 5 figures which can be a combination of images, graphs, tables, scales, instruments, or surveys (optional). A protocol may be uploaded here, if available
- Ethical approval and Clinical Trial approval, if available

Who needs to provide Host Institution Letters of Support?

Host Institution Letters of Support need to 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.

Do Co-Applicants have to sign-off the application?

Each Co-Applicant is invited to view the application form online and approve content prior to submission.

Do I need to contact the Dean of Research to sign off on my application?

As part of the online application process, you will be asked to select the **Dean of Research or equivalent person** authorised to endorse research grant applications for your Host Institution. Their approval is necessary to allow the application to be submitted to the HRB. **Please note that as part of the online system the Host Institutions will approve and submit each application on behalf of the applicant.**

When the application is submitted for approval online, emails are sent to the selected signatory informing them that their approval is requested. If a signatory rejects the application the Lead Applicant will be notified, along with any feedback the signatory has supplied. The application can then be amended and re-submitted; it will be returned to the signatory who made the rejection and continues through the approval process as before.

When signatories approve the application, it will be sent automatically to the HRB to be considered for funding, a grant application number will be assigned to the application and a confirmation email will be sent to the Lead Applicant.

6. Submission

How will I know that my application has been successfully submitted?
Once the HI endorses your application it will be sent automatically to the HRB to be considered for funding, a grant application number will be assigned to the application, and you will receive a confirmation email.

I have submitted my application but have just realised I have amendments to make; can I amend the application?
No. Once you have submitted your application, you cannot edit or unsubmit it.