

Definitive Interventions and Feasibility Awards (2020) Frequently Asked Questions

What are the key changes to the Definitive Interventions and Feasibility Awards for 2020?

- Increased budget cap for individual studies (DIs): up to €1.2m where justified
- Additional resources if including a Study Within A Trial (SWAT), additional €20,000 budget allowance
- Co-Lead Applicant option, to allow more Health and Care Practitioners to take a leadership role
- Applicant Team: more Co-applicants allowed, to a combined total of 15 Co-applicants and Collaborators
- Mandatory engagement with lead Host Institution to undertake a risk assessment review of all Full Applications
- International studies: further justification needed, limits to per patient costs outside of Ireland

How do I apply for a HRB Definitive Intervention and Feasibility Award?

Full application stage is by invitation only following the DIFA 2020 Pre-Application Panel review which took place in March 2020.

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.

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

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 (see Appendix II of Guidance Notes). It is critical therefore that the Lead Applicant leaves 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.

Can a health and care practitioner investigator act as lead applicant?

Where a health and care practitioner investigator wishes to lead an application and does not have the required academic track record to apply as Lead Applicant the applicant team may designate **two Co-Lead Applicants**, *at least one of whom must be a health and care practitioner practising in Ireland*. One or both will have to fulfil the typical requirements of a HRB Principal Investigator in terms of the

expected academic track record (as set out in the eligibility requirements). Both are expected to demonstrate relevant experience and expertise in clinical trials and other interventions.

Can applicants submit more than one application in a peer review cycle?

No, only one application per Lead Applicant/Co-Lead Applicant will be considered in a peer review cycle. 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.

Can a Lead Applicant-Researcher in a tenured academic post request a salary?

No, the salary and related costs of academic staff within research institutions (including buy out from teaching time etc.) will not be funded. If Lead Applicants who are in an academic post request salary the application will be deemed ineligible.

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/Co-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.

Can a PI submit more than one application (as the lead)?

A PI may not be the lead applicant of multiple applications. Only one application per Lead Applicant/Co-Lead applicant to this scheme will be considered.

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

No, co-lead applicant is considered the same status as lead applicant and thus the rule applies of only one application per Lead Applicant/Co-Lead applicant to this scheme will be considered.

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 DIFA 2020?

Per patient costs outside of Ireland will not be eligible costs for the DIFA scheme. 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 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 SWAT (Study within a Trial)?

An additional €20,000 (inclusive of overheads) can be applied for if conducting a SWAT study. Please note that individual proposed SWATs may cost more or less than €20,000; actual costs should be included. The additional budget allowance for SWATs is to encourage and support further SWATs within the HRB-funded portfolio.

Co-Applicants and Collaborators

How many Co-Applicants/Collaborators can I have?

The DIFA 2020 round will allow for more flexibility between number of co-applicants and collaborators on the application, 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 can I have?

The maximum number of co-applicants allowed is 10, up to a maximum of 15 co-applicants/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.

Submission and Host Institution Signatory

What documents should be uploaded with my application form?

You must upload the following documents:

- Objectives and Deliverables Gantt Chart
- Letter of Sponsorship
- Host Institution Letters of Support, if applicable (see next question)
- Collaborator agreement forms, if applicable (required for all collaborators)
- Infrastructure agreement forms, if applicable
- Ethical approval and Clinical Trial approval, if available.

You may also upload 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. A protocol may also be uploaded, if available.

Who needs to provide Host Institution Letters of Support?

Host Institution Letters of Support need to be provided for (1) Lead Applicant(s) in a contract position and (2) Co-Applicants in a contract position who are seeking their own salary

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.

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.

Will there be a DIFA Applicant Workshop at the HRB this year?

Due to the situation with Covid-19 we will not be holding a DIFA Full Applicant Workshop at the HRB this year, but a pre-recorded Webinar and information pack will be circulated to all Full Applicants in late April.

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 retract it.