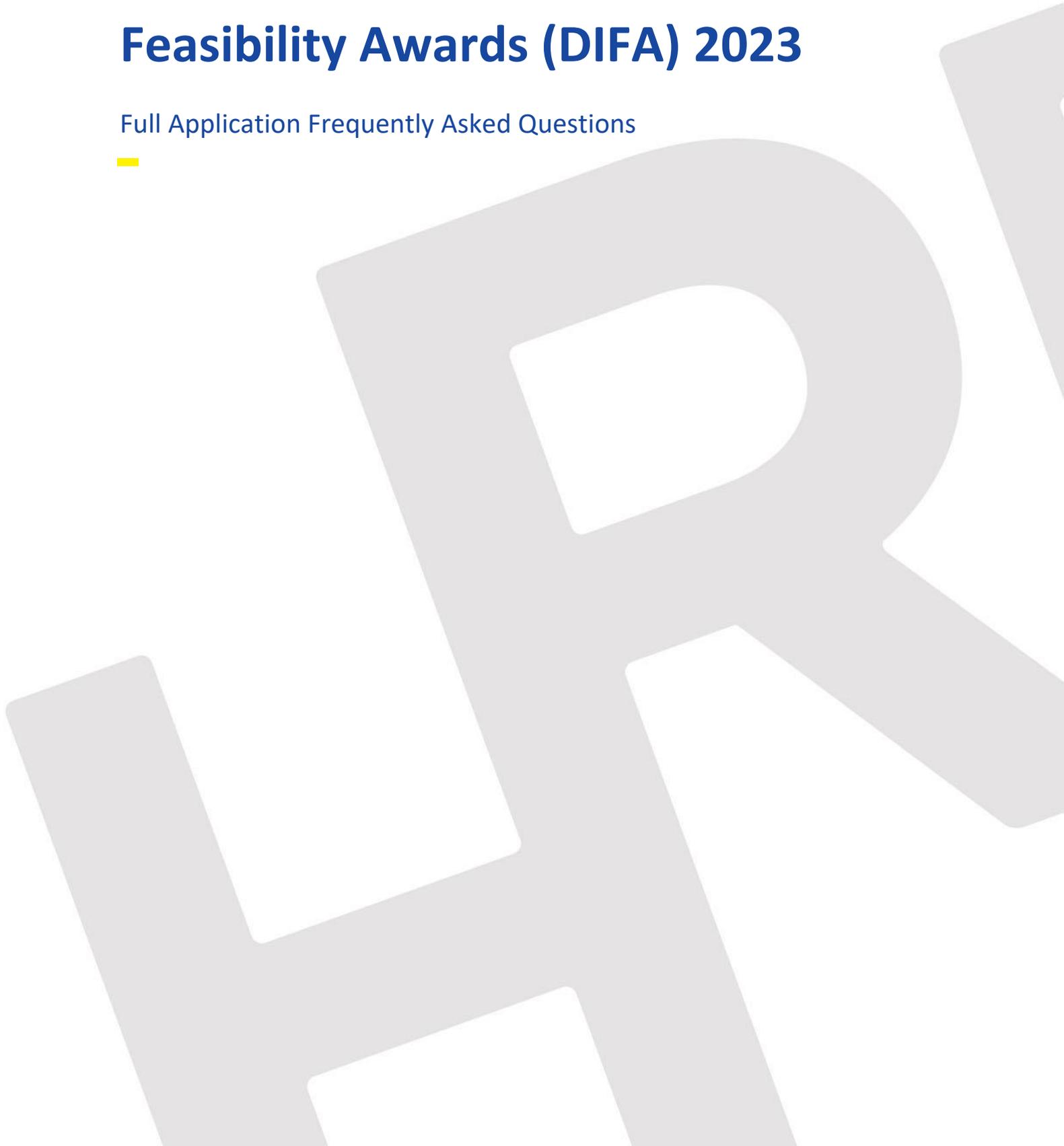


# Definitive Interventions and Feasibility Awards (DIFA) 2023

Full Application Frequently Asked Questions



## HRB DIFA 2023

### Frequently Asked Questions

#### GENERAL

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

Full application stage is by invitation only following the DIFA 2023 Pre-Application Panel review which took place in June 2022.

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. 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?**

All applications must be submitted to the HRB by using HRB GEMS by **15 September 2022 at 13:00**.

#### SCOPE OF DIFA 2023

##### **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 2023?**

Costs associated with trial activities outside the island of Ireland are not 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.

## **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.

### **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.

## CO-APPLICANTS AND COLLABORATORS

### How many Co-Applicants/Collaborators can I have?

The DIFA 2023 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/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.

## **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.

## **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.