

HRB-SFI Translational Research Award Programme Frequently Asked Questions (FAQ)

1. Eligibility

Q 1a: I am currently a PI in a Higher Education Institution (HEI) outside the Republic of Ireland. Am I eligible to apply to the TRA 2011 Programme?

To be eligible to apply, a PI/co-PI must be a researcher recognised by a host institution in the Republic of Ireland as an independent investigator, who will have an independent office and lab space *for the duration of the award*. This agreement must be in place upon submission of an application to this call but the researcher does not need to be officially in place at the HEI until the commencement of the award.

Q 1b: What is the definition of a clinician investigator?

A clinician investigator is defined as a Health and Social Care Professional who is engaged either wholly or partly in clinical service provision, and actively engaged in research. They may also have an academic affiliation. Health and Social Care Professionals include medical practitioners, dentists, nurses, midwives, pharmacists and those professional groups recognised under the Health and Social Care Professionals Act 2005.

Q 1c: Must the clinician investigator have a medical qualification?

No. A clinician investigator must be a Health and Social Care Professional which includes medical practitioners, dentists, nurses, midwives, pharmacists and those professional groups recognised under the Health and Social Care Professionals Act 2005.

Q 1d: Does the clinician investigator have to be based in the Republic of Ireland i.e. what if there is no suitable clinician based in an Irish hospital to partner in an application?

The clinician investigator must be based in an Irish clinical setting and be actively engaged in research.

Q 1e: I was awarded my PhD in 2005. Am I eligible to apply?

Yes. The official date is defined as the year that the degree was conferred, i.e., the year printed on the official PhD/MD certificate. Verification of this official date by the awarding research body must be available upon request. The number of years is determined per calendar year. Therefore, only individuals with an official date of 2006 or prior are eligible to apply).

Q 1f: How do HRB and SFI define Senior Author for TRA?

A senior author is one who is listed as first or joint first author, reflecting the fact that he/she has provided the greatest intellectual contribution, has held the primary responsibility for collecting and analysing data, and for the writing of the manuscript and associated drafts. The last author will also be considered as a senior author, since this position generally reflects his/her overall responsibility for the study and suggests that a level of mentorship has been provided.

It will be noted that different publishers have differing rules on how the senior authorship is indicated (e.g., by using asterisks, underlining, placing the name first or last in the list of authors, etc.); of overriding importance however is that the applicant should be able to convince and reassure reviewers that they are the key author on these publications.

Please note that senior authorship does NOT necessarily mean that they were responsible financially for the research that was reported.

Q 1g: I have recently submitted an application to the SFI Principal Investigator Program (SFI PI 2011). Am I eligible to submit a proposal to the TRA 2011 Programme?

If you are an applicant/co-applicant whose proposal is *currently* under review in the SFI RFP 2011 or the SFI PI 2011 call, then you may submit a proposal for consideration to the TRA 2011 programme.

Under the terms of the award, PIs/Co-PIs *currently* funded under other HRB or SFI award programmes are also eligible to apply to the TRA 2011 Programme. Examples include but are not limited to the HRB CSA or TRA Programmes, and the SFI PI, PICA, PIYRA, SRC or CSET Programmes.

Conversely, applicants who submit an application to the TRA 2011 call are also eligible to apply to other HRB and SFI programmes.

Please note that the content of the application being made to the TRA programme must be distinct and bear no overlap with another proposal from the same PI/co-PI that is either under consideration or currently funded, although it will be anticipated that similar scientific backgrounds will underpin both proposals.

Please also note that sufficient justification must be provided in the full application, if invited, for holding two major awards.

Q 1h: I have funding through the SFI SIRG Programme, yet there is no specific reference to my eligibility in the TRA 2011 call document. Can you clarify my position in relation to making an application?

As a SIRG award holder, you may *not* apply to other SFI award programmes until you are *in the last 18 months of your award*. It would be acceptable, however, for you to be a collaborator on a TRA proposal of one of your colleagues. At this point, that is the only way in which you could have involvement in this programme.

2. Principal Investigator, Co-Principal Investigator, Funded Investigators and Collaborators

Q 2a: Can there be more than one Co-PI on the application?

No, applications require the pairing of two Principal Investigators – one academic and one clinician investigator. One of these will act as PI and the second will act as Co-PI for the purpose of this call.

Q 2b: Is there a limit to the number of applications I can submit?

Yes. Only one application per investigator/co-investigator will be considered in this call.

Q 2c: Can I be a Funded Investigator on more than one application?

No. Funded Investigators may only participate on a single application. In addition, individuals submitting an application as PI or Co-PI cannot be nominated as a Funded Investigator on another proposal. Where an Investigator is nominated on more than one application as PI, Co-PI or Funded Investigator, the applications will be returned without review.

Q 2d: I am a clinician in an academic position. Is it necessary for me to form a partnership?

Yes. You must decide which partner you will represent within the application i.e. the academic or clinician partner. You cannot be both.

Q 2e: What is the definition of a funded investigator?

A Funded Investigator will play a significant role in a work-package within the TRA. Funded Investigators will serve under the direction of the PI or Co-PI and may receive funding for items such as running costs and personnel. A Funded Investigator will not receive support towards his/her own salary. The Funded Investigator designation should be a reflection of the level of input of the individual to the research award, and take account of the career stage of the investigator. The Funded Investigator role is optional and we would typically expect no more than 1-2 Funded Investigators for an award of this size. A funded investigator is distinguished from a collaborator in that they receive a budget allocation from the award, are directly supervising a team member(s) and provide a greater overall level of input to the research project than a collaborator.

The identity of a Funded Investigator may change between the pre-proposal and full proposal, however, it cannot change between full application and notification of funding.

Q 2f: Can my application include an industry partner(s)?

Yes. The HRB-SFI recognises the value that such partnerships can bring. If you have an industrial partner(s) and are submitting a pre-proposal application, no additional details than those requested in the pre-proposal Application are required.

If you have an industrial partner(s) and are making a full application, you will need to upload a completed HRB-SFI Collaborator Agreement Form. This will confirm their commitment to collaborate for the duration of the study and their agreement that all the data from the study can be placed in the public domain within a reasonable timeframe.

An industry partner need not necessarily be confined to one that is based in Ireland, but should include the most appropriate industrial partner that can be justified scientifically.

Please note that Industrial collaborators will not receive funds from an award if made.

Q 2g: Can a PI and Co-PI be based at the same Institution, if that institution includes a hospital where the clinician is based?

Yes. The applicants will need to decide who takes the designation of PI or Co-PI for the purpose of the proposal.

Q 2h: Is there a limit to the number of collaborators that can be associated with the application?

No. There can be as many collaborators as is required provided sufficient justification is made for each of their roles.

Q 2i: Does the Funded Investigator have to be employed at the same Host Institution as the PI or Co-PI?

Funded Investigators do not need to be employed by the same Host Institution as the PI or Co-PI.

Q 2j: Can a PI, Co-PI or Funded Investigator be a collaborator on another application?

Yes but only if their involvement as a collaborator on another project is fully justified.

3. Salaries and Budgets

Q 3a: What is the expected duration of grants under this scheme?

A maximum of 4 years funding will apply but please note that a typical translational research project would be 2-3 years in duration. You must apply for the resources and timescale appropriate to the research proposed.

Q 3b: I am a post-doctoral researcher on a contract; if I apply to the HRB-SFI Translational Research Award 2010 Programme can I request my own salary?

No. PI / co-PI or funded investigator salaries are not an eligible cost. However, a PI or Co-PI that is a clinician investigator can request costs required to secure protected research time. Costs associated with securing protected time of clinician investigators can only be claimed where actual costs arise through back filling of posts. It is expected that this would be only a minor component of a TRA award unless well justified. Please contact the HRB for further guidance

Q 3c: Do I need to include a budget in my pre-proposal application?

No. Applicants who are successful at pre-proposal stage will be asked to submit a detailed budget with their full proposal application.

4. Scope

Q 4a: Can you explain what is meant by ‘mechanisms of human disease’ in the context of Patient-Oriented Research?

‘Mechanisms of human disease’ in the context of Patient-Oriented Translational Research refers to where targets (or disease processes) of interest have already been identified which underpin the particular ‘mechanism’. Therefore, applications made to the TRA Programme will use this platform of *prior discovery* to further develop their findings into innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease.

Q 4b: Will the HRB-SFI TRA Programme fund clinical trials?

Studies involving early phase First-in-man to Phase I clinical trials are eligible under this scheme, however, applications beyond the early translational focus of the call are not eligible e.g. late stage clinical trials or clinical trials for the purposes of product development or optimisation.

The HRB-SFI TRA Programme will not fund applications which are solely for the clinical development, such as the safety and/or efficacy testing of therapies, diagnostics or devices.

5. Ethics and governance

Q 5a: Do I need full ethics permission and regulatory approvals for any animal/human studies in the grant proposal? If so, when should I apply for this?

The HRB-SFI does not require ethics permissions and regulatory approvals to be in place when you submit an application. However, given that research requiring the use of human tissue/organs may raise various ethical and regulatory issues, applicants will be required to demonstrate that they have adequately considered these matters. Early discussions with regulatory bodies may be required to ensure that all requirements can be met in a timely manner. If an application is successful, it is the responsibility of the Host Institution to ensure that necessary approval is

obtained from an ethics committee(s) recognised by the Host Institution. Documented proof of ethical approval will be required prior to release of funds.

Q 5b: Where the PI and Co-PI belong to separate host institutions, are both institutions required to sign off on the application?

No. The award will be administered by the host institution of the nominated PI only.

6. Project Management and Milestones

Q 6a: What is a milestone?

Within the framework of project management, a milestone is the end of a stage that marks the completion of a work package or phase, typically marked by a high level event. In addition to signaling the completion of a key deliverable, a milestone may also signify an important decision or the derivation of a critical piece of information, which outlines or affects the future of a project. In this sense, a milestone not only signifies distance traveled (key stages in a project) but also indicates direction of travel since key decisions made at milestones may alter the route through the project plan.

Each milestone should be defined by specific criteria and their associated quantified target values that can be used to determine if the milestone has been met. ***SMART goals should be used as a guide when designing the project milestones to ensure that they are specific, measurable, attainable, realistic and timely.***

Meeting milestones is a pre-requisite for project progression.

Q 6b: What happens if milestones are not met?

If a milestone is not met, then the project team should submit a remedial plan of action to HRB-SFI as part of the Milestone Report. Projects which show negative results at milestones, or which fail to meet milestones, will be terminated, unless acceptable remedial plans are submitted.

For example, in a project funded for up to 3 years, a 12 month milestone that is not met will result in the project being terminated at this point.

7. Application

Q 7a: Can I include Figures to support my pre-proposal application?

Yes. However, figures should not be embedded in the text but must be uploaded as a separate file where indicated on eGrants.

A maximum of **one** supporting Figure or Table can be uploaded as an attachment. A figure may be composed of a maximum of 3 parts (A – C).

Q 7b: Does the 1200 word maximum for the project description exclude the questions?

Yes. You may include the questions posed by HRB-SFI as part of your project description but these will be excluded from the total word count.

Q 7c: Do I need to submit CVs for Funded Investigators and collaborators at pre-proposal stage?

At pre-proposal stage you must submit CVs for known Funded Investigator(s). Collaborator CVs are only required with full proposals.

Q 7d: Where do I find my ‘Application Reference Code’ which is required on the signature page?

The application code is assigned as the applications are submitted. Once the applicant has hit the submit button, they can re-open the submitted application and view the application code at the top right of the eGrants application form.

Q 7e: Can I submit signatures on separate copies of the signature page?

No, all signatures must be on a single copy of the signature page. It is up to the applicants to ensure that signatures can be arranged in a timely fashion through early consultation with their Research and Technology Transfer Offices. All signatures on the signature page must be originals. Faxes or electronic signatures are not acceptable.

Q 7f: Are electronic signatures acceptable for any of the supporting documents?

Electronic signatures are acceptable for letters of support which are uploaded onto eGrants but they are not acceptable for the signature page. All signatures on the signature page must be originals.