



HEALTH RESEARCH BOARD and SCIENCE FOUNDATION IRELAND

Translational Research Awards 2011 (TRA 2011)

Guidance Notes

Key Dates & Times

Application Call	04 March, 2011
Application Closing date (pre-proposal)	14 April 2011, 13:00
Submission of signature pages (pre-proposal)	21 April 2011, 15:00



HRB SFI Translational Research Awards 2011

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HRB-SFI Translational Research Awards 2011

Guidance Notes

1. Introduction

The Health Research Board (HRB) and Science Foundation Ireland (SFI) recognise the critical importance of translational research in advancing basic research findings from bench to bedside and have therefore established a joint initiative in Translational Research.

The HRB has the lead role in bridging the gap between new health research discoveries and the effective translation and implementation of these discoveries into policy and practice in order to achieve specific health service goals. We work with others to build the capacity for health research, create opportunities for researchers, drive the translation of research discoveries into delivering improved healthcare and provide solid evidence to support health research policy. This, in turn, will achieve better outcomes for patients and realise efficiencies in the health service.

SFI advances national scientific progress by awarding grants for research on a competitive basis in those fields of science and engineering that underpin biotechnology (BIO), information and communication technology (ICT), and sustainable energy and energy efficient technologies (ENERGY). SFI funds internationally recognised world class research and recognises that the research excellence of an application is paramount.

The Translational Research Award (TRA) joint initiative aims to support the research funding strategy of both the HRB and SFI (HRB-SFI) with reference to the Health Action Plan 2009¹. The initiative focuses resources in areas which offer the greatest potential for translation into impacts and benefits for health and long term economic development, as well as for more efficient and effective collaboration between researchers based in an academic setting and those working in a service delivery/clinical setting who are engaged in translational research (e.g. training for academics in skills relevant to translational research). In keeping with the strategic goals of HRB and SFI, these awards will fund investigator-driven research projects with clear milestones and realistic deliverables.

The HRB-SFI is now inviting applications for its 2011 TRAs.

¹ *Action Plan for Health Research 2009-2013 (Department of Health & Children)*

1.1 Objectives

The objectives of the HRB-SFI TRA 2011 are to support translational research which for the purpose of this call is defined as:

Internationally competitive and innovative research that is specifically concerned with the conversion of basic research findings into innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease.

Translational research in this context is milestone-driven, focused on a well defined goal and delivered with maximal efficiency and minimal risk.

Additional objectives include:

- To support excellence in research as measured by international merit review
- To promote new and strengthen existing partnerships between basic and clinical scientists and between academic and industry/charity sectors to expedite the translation of basic research outputs to the clinic and marketplace
- To lead to improvements in the health and well being of the Irish nation.

1.2 Scope

The TRA 2011 is specifically focused on areas of strategic importance to Ireland's healthcare needs and long term economic development including:

- *Patient-Oriented Research*
- *Medical devices*
- *Diagnostics*
- *E-health*

Definitions of these areas are included in Appendix I and should be considered in the context of Translational Research as defined for this call. The TRA scheme will focus on **early translational research only** (see Translational Continuum in Appendix II).

The scheme will not fund:

- Applications which are solely **or** predominately basic biomedical research. For the purposes of the call, basic biomedical research is defined as research conducted to increase the knowledge base and understanding of the physical, chemical and functional mechanisms of life processes and disease but not directed to solving any particular biomedical problem in humans or

animals. Note that applications seeking to investigate basic disease mechanisms outside the context of translational research will not be considered

- Applications seeking to discover new causes or risk factors of disease, biomarkers, drug targets, biomaterials or research tools. Such discoveries will be considered as the foundations for a translational award
- Applications which are solely for clinical development of therapies or diagnostics i.e. applications beyond the early translational focus of the call, such as phase II or later clinical trials
- Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Note: For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HRB-SFI cannot take on the role of sponsor so plans for appropriate sponsorship arrangements must be included in the application.

2. Definitions of Investigators and Collaborators

The **Principal Investigator (PI)** will serve as the primary point of contact for the HRB-SFI on the award and during the review process. The PI has primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of the HRB-SFI. Both the PI and Co-PI will be responsible for the scientific and technical direction of the research programme and the submission of reports to the HRB-SFI.

The **Co-Principal Investigator (Co-PI)** has a well-defined, critical and continuing role in the proposed investigation. For the purposes of eligibility, reviewing and monitoring, a Co-PI applying for funding under the HRB-SFI TRA 2011 programme will receive equal evaluation as the PI and will hold equal accountability for the delivery of the proposed research objectives and milestones. In this documentation the terms and conditions for 'PI' and 'Co-PI' are interchangeable.

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.

An **official Collaborator** is an individual who is committed to providing a focused contribution for a specific task. The collaborator will serve under the direction of the PI or Co-PI and will not receive funding through the award. Involvement of a collaborator may add value to the project (e.g. through provision of additional funding, reagents, materials, expertise or access to technologies); facilitate patient input or involvement; assist with patient recruitment; contribute to the dissemination of the results of the research. Collaborators can be based in an academic institution, a private enterprise, a

healthcare organisation or agency, or come from the charity sector. If involved in genuine scientific collaboration, industrial partners may be included as official collaborators. Industrial collaborators will, in general, be expected to meet their own costs and in cases where they are supplying kits, materials etc they should be provided at no cost to the research teams.

An individual contributing to the research proposal, but not sufficiently involved to warrant listing as an official collaborator or Funded Investigator, can be listed within the text of the research proposal.

CVs must be provided for ALL official collaborators at Full proposal stage. In addition, each official collaborator must provide a Collaboration Agreement Form with the full grant application and this must clearly outline the role of that collaborator in the programme of research proposed. The role of the collaborator must also be referenced in the main body of the research proposal (For example: *Will the collaborators be supplying samples, data, etc? Will the collaborators be providing training in techniques or the use of equipment? Will the collaborators directly participate in specific work projects? Will collaborators be acting in a purely advisory capacity?*).

3. Eligibility Criteria of Applicant

Please note that the CV template section of the application form must contain evidence of eligibility based on the criteria outlined below. If evidence of eligibility is not provided, the application will be returned without review. Please note that the HRB-SFI will not follow up with applicants where evidence of eligibility has not been provided.

Applications to this scheme require the pairing of a PI and Co-PI, including an investigator based in an academic setting and a clinician investigator², in order to develop the project along the translational research continuum to or towards a clinical application. Successful applicants will need to demonstrate an effective transfer of expertise in the direction of bench to bedside.

One applicant and Host Institution (eligible academic institution or clinical setting in the Republic of Ireland) will be nominated as the main contact for all communications. The grant will be administered through the Host Institution of the nominated PI only.

The PI and Co-PI must:

- Have at least **5 years**³ of independent research experience beyond the PhD, MD or equivalent⁴ by the pre-proposal deadline

² For the purpose of TRA 2011 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.

³ 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.

- Be **senior author** on a **minimum of seven international peer reviewed articles**⁵. Only original research publications, and not review articles, are acceptable.
- Have demonstrated research independence through securing at least one peer-reviewed, independent research grant as a Lead investigator or as Co-Investigator (i.e. of equal status to the Lead Investigator on the application) over the last ten years. For the purpose of this scheme, travel awards and career Fellowships or Scholarships (which only include the salary of the PI and not research team costs) are **not** considered ‘independent’ research grants. Furthermore, awards where the PI or Co-PI holds, or has held, the position of “Collaborator” **will not** be accepted.

Funded Investigator(s) must:

- Hold a Ph.D/M.D. or equivalent² for at least **3 years** by the pre-proposal deadline (i.e. degree must have been awarded in 2008 or prior)
- Be **senior author** on **a minimum of three international peer reviewed articles**⁵. Only original research publications, and not review articles, are acceptable.

The PI, Co-PI and Funded Investigator are expected to have the capability and authority to mentor and supervise team members, including postgraduate-level students if these are to be included as members of the proposed research team.

In addition, the PI, Co-PI and Funded Investigator(s) must:

- Hold a post (permanent or a contract that covers the duration of the award) in a recognised research institution in the Republic of Ireland (the “Host Institution”) as an independent investigator, **or**
- Be a contract researcher with a contract that covers the period of the grant, who is recognised by the Host Institution as an independent investigator and will have an independent office and research space at the Host Institution for which he/she will be fully responsible for at least the duration of the award **or**
- Be an individual who will be recognised by the Host Institution upon receipt of the award as a member of the academic staff or as a contract researcher as defined above for at least the duration of the award. The applicant does not necessarily need to be employed by the Host Institution at the time of proposal submission.

For PIs, Co-PIs or Funded Investigators holding contract positions, a Letter of Support from the Head of School/Research Centre/Hospital **must** also be included. The formal letter on headed notepaper and signed by the Head of School/Research Centre must include the following declaration:

[*Research body name – insert name*] which is the host research body of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds, or will hold, an employment contract which extends until [*insert date; contract must not expire prior to proposed end date of award*]; (ii) has an independent office and research space/facilities for which he/she is fully responsible for at least the

⁴An equivalent qualification and/or demonstrated research accomplishments may be accepted in exceptional circumstances **and must be approved in advance by HRB-SFI.**

⁵ Consult FAQ 1f regarding the definition of “senior author”.

duration of the award, and (iii) has the capability and authority to mentor and supervise post-graduate students and post-doctorate researchers. Electronic signatures are acceptable for letters that are uploaded on the eGrants system.

In the case of PIs with a permanent post, the permanent nature of the position must be indicated in Section 1 of the CV template.

Host Institution sign off (signature page and Letter(s) of Support where applicable) serves as their endorsement of the eligibility of the PI, Co-PI and Funded Investigator (if applicable), as well as approval of the budget requested (Full proposal), the infrastructure to be provided by the research body, and confirms the validity and accuracy of the details provided in relation to the current, pending and expired awards as detailed in Section 3 of the PI/Co-PI CV. Host Institution sign off furthermore confirms that the clinician investigator is free to devote the stated time to the Programme.

Only one application per investigator will be considered in this round. Applicants who submit an application to the TRA 2011 call are also eligible to apply to other HRB and SFI programmes. Please note that projects that are submitted to other HRB or SFI calls by the same PI/Co-PI **must be distinct and bear no overlap**. However, it is acknowledged that there may be similarities in the subject area/scientific background underpinning applications. PIs/Co-PIs applying simultaneously to other programmes at HRB and/or the SFI may be less competitive if it is deemed that they do not have sufficient capacity and/or experience to justify running two substantial concurrent research programmes.

PIs currently funded under other HRB or SFI award programmes are also eligible to apply. PIs/Co-PIs funded under the HRB or SFI programmes (e.g. HRB CSA or TRA and SFI PI, PICA, PIYRA, SRC or CSET) should note that progress on the existing award will be assessed if they submit an application to the TRA 2011 Programme. Therefore, individuals who have received HRB or SFI programme awards recently may be deemed to be less competitive.

Individuals who are funded as either PI or Co-PI under these programmes **must provide** justification at the full proposal stage for concurrently holding a major HRB or SFI award and a TRA 2011 award.

Applications including collaborations with Industry and Charity sectors are strongly encouraged where these add value to the project, for example through provision of additional funding, reagents, materials, expertise or access to technologies. The terms of collaboration, particularly in relation to industry must be reviewed with the institution's technology transfer office or equivalent. Collaboration arrangements should ensure transparency in the project design and in the analysis of results. Consideration should also be given to issues such as intellectual property rights, access to data and samples etc. See section on IP management for further details.

Note: In view of the overwhelming evidence that both active and passive smoking of tobacco are injurious to health, the HRB is unwilling to fund applications from individuals applying for, holding, or employed under a research grant from the tobacco industry.

4. Eligibility of Host Institutions

The Host Institution is the body in charge of the financial and administrative co-ordination of the research project receiving a research grant from the HRB-SFI. **Host Institutions must be situated in the Republic of Ireland.** The award will be administered by the Host Institution of the nominated PI. Queries regarding eligibility of Host Institutions should be directed to HRB-SFI prior to submission. The list of approved Host Institutions is located at the following link:
<http://www.hrb.ie/research-strategy-funding/grant-holder-information/host-institution-policiesforms/approval-of-host-institutions/>

5. Funding

HRB-SFI TRA awards will be up to €250,000 direct costs per annum with a maximum award size of €1 million. **Funding will be milestone-based i.e. negative results at milestone or failure to meet milestones will result in grant termination.** The requested award duration should reflect the nature of the proposed research but should not exceed four years. Please note that the typical duration of a translational research project is 2-3 years.

Projects that successfully meet all milestones up to the mid-point of the award will undergo a scientific and strategic review. Completion of a successful review is required to ensure continuity of funding in addition to successfully meeting all milestones and deliverables.

Since this is a milestone-driven award where success will determine a continuum of funding, a full four-years funding for PhD student training cannot be guaranteed. In this regard, the HRB-SFI would like to highlight that this award may be suitable for the training of Masters or postdoctoral researchers in translational research. However, if a PhD student is enrolled on the award, the HEI must guarantee the financial support of the student for the full duration of their doctoral research. **It is the sole responsibility of the PI and Co-PI to design an appropriate team structure to ensure that all milestones and deliverables are met.**

The budget requested should be appropriate to the proposed work, taking into account the experience and recent research funding record of the applicant(s).

Note: The HRB-SFI does not fund the salary and related costs of academic faculty within research institutions (including buy out from teaching time etc.).

The HRB-SFI funding supports the research programme costs of the PIs and their research groups.

Eligible costs include:

- Relevant research expenses, including equipment where justified, running costs & dissemination
- Only equipment purchases that are directly required for the research and are deemed not to be easily accessible elsewhere in Ireland are appropriate
- Contributions to salaries/stipends for staff hired specifically to carry out the research programme. PI/Co-PI or Funded Investigator salary is not an eligible cost. However, requests for costs associated with securing protected research time of clinician investigators will be considered. This does not apply to the role of Funded Investigator
- Access to necessary special facilities which are not available in the host academic or clinical institutions.

The following costs are *examples* of ineligible costs: **PI, Co-PI, Funded Investigator or Collaborator salary**; teaching buyout; contingency or miscellaneous costs; maintenance contracts on equipment; hospitality and entertainment costs; technology transfer or patent costs; conference and workshop organisation costs; journal subscriptions; relocation expenses.

In addition, the HRB-SFI will also make an indirect or overhead **contribution** to the host institution, which is calculated as a percentage of the direct costs (excluding equipment and fees). Overheads are payable as a contribution of 30% to the Host Institution for the indirect costs of hosting the HRB-SFI-funded research programme and are intended to enable the Host Institution to develop internationally competitive research infrastructure and support services.

6. Intellectual Property Management

Information on IP guidelines can be found in the Intellectual Property Management Guidelines on the SFI website (<http://www.sfi.ie/funding/grant-policies/intellectual-property-management-guidelines/>). For awards involving more than one research body, a joint IP agreement should be in place between the relevant institutions. In the absence of a joint IP agreement, the management of any IP remains the responsibility of the host institution.

7. Project Management

To ensure successful delivery of the proposal's objectives, successful applicants will be required to establish appropriate project management systems and to submit to HRB-SFI Six-monthly, Milestone, Annual and End of Grant Reports. If a milestone is not met, the project team will be required to 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.***

8. Application Procedure

Please read application guidelines carefully. Where applicants ignore these guidelines and exceed word and/or figure limits, applications will be returned without review. The HRB-SFI will not entertain any appeal process on this.

All applications must be made online using the HRB eGrants System.

The TRA 2011 scheme will consist of a two stage application process consisting of:

Stage 1: Open call for submission of pre-proposals

Stage 2: Invitation to selected applicants to submit full proposals

8.1 Stage 1: Pre-proposal

TRA 2011 applicants must first submit a pre-proposal application. All applications must be made online using the HRB eGrants system. The purpose of the pre-proposal stage is to ascertain whether the project's aims, objectives and deliverability are internationally competitive, innovative and are appropriate for the scope of the scheme. As outlined in section 9, the strength of the translational element, strategic relevance, applicant expertise and research environment will also be assessed. Successful applicants will be invited to submit a full application.

The HRB-SFI is committed to an open and competitive process underpinned by international peer review. Following an initial eligibility check a Review Committee (which will be comprised of international scientists, clinicians and industrial researchers) will consider applications with a view to making final recommendations to the Board of the HRB-SFI. A limited number of applications (approx. 10-12) will progress to the full application stage.

Individuals may only submit, as PI or Co-PI, one single proposal to an open call of the HRB-SFI TRA Programme. If an applicant submits more than one proposal both applications will be returned without review.

Individuals submitting an application as PI or Co-PI cannot be nominated as a Funded Investigator on another proposal. Funded Investigators may only participate on a single application. Where an Investigator is nominated on more than one application as PI, Co-PI or Funded Investigator, the applications will be returned without review.

The CV template section of the application form must contain evidence of eligibility based on the criteria set out on page 6-8 of this document. If evidence of eligibility is not provided, the application will be returned without review. HRB-SFI will not follow up with applicants where evidence of eligibility has not been provided.

NOTE: Once submitted to eGrants an application cannot be withdrawn and modified for resubmission in the same call regardless of the date of submission.

8.2 Stage 2: Full proposal

Selected applicants will be invited to submit a full application. All applications must be made online using the HRB eGrants System. Full applications will be subject to rigorous international peer review, following which a Review Committee, as per the pre-proposal stage, will convene and recommend the highest quality proposals for funding.

9. Guidance on the Application Forms

These notes must be read in conjunction with the application form and are designed to help you provide the information required. **Applications should be completed in partnership with the Host Institution's Research and Technology Transfer Offices and failure to do so may prejudice the assessment of your application.**

9.1 Pre-proposal Application Form

The pre-proposal application form is divided into the following sections:

Part A (Online) – Details of the PI, Co-PI, Funded Investigator(s) (if applicable) and Host Institution in addition to project keywords and summary must be completed online.

Part B (Offline) – The following sections should be completed offline using the templates provided and should be subsequently uploaded to eGrants: Project Description, Project Team and Investigator CVs.

9.1.1 Part A – Online form

PI and Co-PI Details

Includes name, contact information and other requested details.

Host Institution

Selected from dropdown list of eligible host institutions.

Funded Investigator names (if known)

The Funded Investigator role is optional and we would typically expect no more than 1-2 Funded Investigators for an award of this size. Please note that the identity of a Funded Investigator may change between the pre- and full-proposal stages but may not change between submission of the full application and notification of funding.

Keywords

Please use up to five keywords that specifically describe your area of research.

9.1.2 Part B – Offline form

Note that the MS Word template for Part B can be downloaded from the eGrants site. It is completed offline and then uploaded to eGrants as part of the completed application form prior to submission.

Project Abstract

This should be a succinct summary of the proposed research. The aims and hypotheses of the project should be conveyed with clarity. The objectives of the project and what the work is expected to establish should be described. Ideally it provides a clear synopsis of your proposal and should set the research proposal in context.

Project Description

Note: The word limit will be strictly enforced. HRB-SFI reserve the right to return applications exceeding word limits.

The Project Description (**1200 words**) should include a brief description of the proposed research addressing the following questions:

- What is the research discovery to be translated including the current state of validation? What are the competing solutions and their developmental status? What is the competitive advantage of the proposed solution?
- What unmet health need will the research address and what is the potential impact on healthcare and the Irish economy?
- What approach or methodology will be used?
- What is the defined endpoint to this project and describe the available resources and facilities that are required to reach this endpoint? Include at least two milestones (one being the project end point)
- What is the current status of any IP relating to the proposed project? Describe any freedom to operate issues that have been identified and how they will be addressed

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 (See FAQ 7a for further details).

References

A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of 10 publications.

Sponsorship for Clinical Trial Applications

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HRB or SFI cannot take on the role of sponsor so plans for appropriate sponsorship arrangements (if known) should be included in the application.

Project Team Details:

Role

Outline the role of the PI, Co-PI, Funded Investigator(s) (if applicable) in the programme of research proposed including percentage of time involved.

Collaborators (if applicable/known)

Provide name(s), role(s), contact information and other requested details. Collaborator CV's are not required at pre-proposal stage.

PI, Co-PI and Funded Investigator CVs

The CV templates provided must be used. Please note that failure to use this template or to adhere to the specified page limits will result in withdrawal of the application from the programme. The CV template includes sections on career profile, publication and funding records. ***Please note that the Publication Listing (Section 2) and Research Funding History (Section 3) sections of the CV template should contain evidence of eligibility based on both categories. If evidence of eligibility is not provided, the application will be returned without review. HRB-SFI will not follow up with applicants where evidence of eligibility has not been provided.***

9.2 Full Proposal Application form

The full proposal application forms are divided into the following sections:

Part A (Online) – Provide details of PI, Co-PI, Funded Investigator(s) (if applicable) and Host Institution. A project summary, keywords and budget details are also required.

Part B (Offline) – This section (project description, project management details, Investigator and Collaborator CVs) is to be completed offline using the template provided on eGrants and subsequently uploaded to eGrants.

9.2.1 Part A – Online Form

PI, Co-PI and Funded Investigator Details

Includes name, contact information and other requested details.

Keywords

Please use five keywords that specifically describe your area of research.

Project Lay Summary

This lay summary is similar to the project abstract in that you are asked to describe what you propose to do, why you think it is important to complete this piece of work and how you are actually going to undertake the research. The difference is that it needs to be written in plain English, such that it is easy to understand, and accessible to a broad non-scientific audience. This summary will be used when providing information to the public on the variety of research funded by the HRB-SFI.

Project Budget

Provide a summary and justification of the costs associated with the project.

The maximum value of an award is €250,000 per annum (excluding overhead contribution of 30%).

A **full detailed breakdown of costings** and **justification for all funding** is required for items listed under each subheading. You are strongly advised to seek guidance from the research office/finance office in the host institution before completing this section of the form. The HRB-SFI will not provide additional funding in the case of either under-estimates or over expenditure.

Funds will be provided for the following:

1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	<p>Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with host institution. Applicants should use the most up-to-date version of the IUA salary scales for researchers (http://www.iua.ie/iua-activities/research.html). Please note employee pension contribution of 5% has already been incorporated into the gross salary figure.</p> <p>Please state the pay scale used and the level and point on the scale. This should be justified accordingly. No annual salary increases will be paid.</p> <p>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</p> <p>Note: The HRB-SFI does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits.</p>

b) Employer's PRSI	Employer's PRSI contribution is calculated at 10.75% of gross salary.
c) Employer Pension Contribution	As of 1 September 2009, the HRB will cease paying a pension contribution for all awards except where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
d) Student Stipend	The student stipend is €16,000 per annum (tax exempt) as recommended by current IUA scales
e) Student Fees	A contribution to fees for students registered for a higher degree will be paid at the 2008/2009 fee levels for the duration of the award. Please note only personnel in receipt of a stipend are eligible to receive a student fee contribution.
2. Running Costs	<p>For all costs required to carry out the research including materials and consumables, the purchasing, transport or disposal of animals, consultancy, transcription costs, access to special facilities where not available etc.</p> <p>An additional amount of funding for equipment can be included in this section. Only equipment purchases that are directly required for the research and are deemed not to be available elsewhere are appropriate. Links to existing clinical research facilities or other relevant infrastructural resources are encouraged. Stand-alone computers <u>will not</u> be funded. All costs must be inclusive of VAT, where applicable.</p> <p>The following <u>ineligible</u> costs will not be funded: training courses/workshops, inflationary increases, cost of electronic journals, maintenance contracts on equipment, hospitality and entertainment costs, technology transfer or patent costs, conference and workshop organisation costs, journal subscriptions, relocation expenses.</p> <p><u>Note: Please see a list of costs that fall within the overhead</u></p>

	<p><u>contribution.</u></p> <p>http://www.hrb.ie/fileadmin/Staging/Documents/RSF/PEER/Policy_Docs/Grant_policies/Policy_on_Usage_of_HRB_Overheads_240108.pdf</p>
3. Dissemination Costs	Reasonable costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes.
4. Overhead Contribution	<p>The HRB-SFI will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs).</p> <p>The following are included in the overhead contribution: recruitment costs, bench fees, animal maintenance, software, contribution to gases, bacteriological media preparation fees, waste fees, bioinformatics access.</p>

Other Funding Sources

Provide details of any other financial support available for this or any other related project in the box provided. Indicate the project title, funding agency and amount of award.

Ethical Approval

Ethical approval is required for all research work funded by the HRB-SFI that involves human participants, human material (including tissue) or animals.

Applicants should allow sufficient time to obtain ethical approval. It is suggested that ethical approval is sought in parallel with submission of an application to the HRB-SFI. Documented proof of ethical approval will be required prior to release of funds.

9.2.2 Part B – Offline form

Note that the MS Word template for Part B can be downloaded from the eGrants site. It is completed offline and then uploaded to eGrants as part of the completed application form prior to submission.

Project Abstract

This should be a succinct summary of the proposed research. The aims and hypotheses of the project should be conveyed with clarity. The objectives of the project and what the work is expected to establish should be described. Ideally it provides a clear synopsis of your proposal and should set the research proposal in context.

Project Description

The Project Description (**7500 words**) for the full application should detail:

- The research discovery to be translated including the current state of development/validation. What are the competing solutions and their developmental status? What is the competitive advantage of the proposed solution?
- The unmet clinical need the research addresses and the potential impact on healthcare and the Irish economy
- The specific aims and primary objectives of the project
- Methodological approach (including sample size, power calculations, access to statistical support)
- How the project will achieve its objectives and defined endpoint
- The skills, resources and facilities that are required to reach this endpoint which should be fully justified.

A maximum of **5 figures** which can be a combination of images, graphs and/or tables may be uploaded as a **single document** on eGrants to support your Project Description.

Note: The Health Research Board Centre for Support and Training in Analysis and Research (CSTAR) is available for assistance and advice on the methodologies. CSTAR can be found at the following link www.cstar.ie

Note: You are advised to ensure that your application is focused and that sufficient evidence is provided to enable the international peer reviewers and grant selection committees to reach a considered judgment as to the quality of your research proposal, its significance and feasibility.

References

A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of 30 publications.

Sponsorship for Clinical Trial Applications

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HRB or SFI cannot take on the role of sponsor so plans for appropriate sponsorship arrangements, i.e. Letter clarifying who is going to act as sponsor for this clinical trial study, must be included in the application.

Milestones, Project Management and IP

Applicants must describe how the project will be managed in order to deliver the milestones and key objectives. At least two milestones must be included (one being the project end point). ***For each milestone please set out the success criteria that will be used to ascertain whether the milestone has been met. For each success criterion, please specify a quantified target value that you will seek to attain and a quantified acceptable value, which if achieved, would support project progression. The***

HRB-SFI recommends using SMART goals as a guide when designing the project milestones to ensure that they are specific, measurable, attainable, realistic and timely.

Applicants should provide details of the current status of any IP relating to the proposed project and describe any freedom to operate issues that have been identified and how they will be addressed. A plan for obtaining follow-on funding and/or commercial exploitation of outputs must be included.

Details of Project Management Group membership must be provided together with a Gantt chart or alternative graphical overview of the tasks to be undertaken.

Details of Project team

Describe the roles of the PI, Co-PI, Funded Investigator and Collaborators. Provide full details of all personnel **to be funded** through this project, with names where available. You must demonstrate clearly that the level and expertise of proposed research personnel matches the ambition and scale of the project and that they possess the necessary breadth and skills in all methodological areas required to deliver the proposed programme of work. Clear and explicit justification is also required for the proposed starting point on the salary scale, particularly for more senior-level positions, and an open and transparent recruitment process must be adhered to.

Host Institution Infrastructure and Support

Describe the infrastructure, facilities and other support available at the various research sites where the research will be conducted.

PI, Co-PI, Funded Investigator and Collaborator CVs

The CV templates provided must be used. Please note that failure to use this template or to adhere to the specified page limits will result in withdrawal of the application from the programme. The CV template includes sections on career profile, publication and funding records.

9.3 Approval by Host Institution

Your signature page for both the pre-proposal and full proposal applications serves as confirmation that the application has been reviewed and/or completed in partnership with your institution's **Technology Transfer Office** and approved by the **Research Office** of your Host Institution prior to electronic submission of your application on eGrants. It indicates their formal acceptance and endorsement of the proposal e.g. to ensure salaries are aligned with practices at the Host Institution and any commercial elements have been reviewed by the appropriate expert(s).

9.4 Submission

Please ensure that you have completed all the relevant sections of the application form. Once you have submitted your application, you cannot edit or remove it.

The deadline for receipt of **pre-proposals** is **Thursday 14 April 2011 at 13:00**.

Only applicants who submit a pre-proposal before the deadline of Thursday 14 April 2011 at 13:00 will be eligible, if invited, to submit a full proposal.

Full proposals that deviate significantly in content from the pre-proposal will be administratively withdrawn without review.

9.5 Signature Page

Signature pages must be signed, dated and sent in hardcopy to **Dr Catherine Gill, Health Research Board, 73 Lower Baggot Street, Dublin 2** no later than **Thursday 21 April at 15:00**. All signatures must be originals. Electronic signatures or faxed copies are not accepted.

Please note that the HRB-SFI will not follow up any supporting documentation related to the application, such as signature page or evidence of eligibility. It is responsibility of the applicant to send all documentation within the stated deadline. If the documentation is not received by the HRB-SFI on time and in the correct format, the application will be deemed ineligible.

10. Application Review Process and Assessment Criteria

The submission of an application to the HRB-SFI shall be construed as consent by the applicant to participate in the peer review process. The HRB-SFI TRA 2011 scheme will use a two phase assessment process. In accordance with this process all eligible applications will be evaluated as follows:

10.1 Pre-proposal

Pre-proposal assessment will be carried out by a review committee of distinguished international scientists, clinicians and industrial researchers.

The principal **Criteria for Assessment** of the pre-proposals are:

- Strength of translational element and strategic relevance

- Scientific quality and innovation
- Expertise and research environment

Following this assessment process, a limited number of applicants (approx. 10-12) will be invited to submit a full proposal to the HRB-SFI. Successful applicants will be notified by mid-July 2011 and will be invited to submit a full proposal. An end of August 2011 deadline will apply for full proposal submission. Feedback will be provided to all applicants upon completion of Stage 1.

10.2 Full proposal

The review process will consist of two stages combining both International Expert Review and Committee Review.

10.2.1 Stage 1 (International Expert Review)

In accordance with the peer-review process used to evaluate proposals submitted to the HRB-SFI, all *eligible* proposals will be forwarded to international experts for evaluation. The HRB-SFI reserves the right to return applications without review where an applicant does not meet HRB-SFI eligibility criteria or where the research programme does not fit within the remit of the HRB-SFI. HRB and SFI will solicit reviews of proposals from at least three peers with expertise in the subject areas of the proposed research. Selection of reviewers shall be at the sole and exclusive discretion of the HRB-SFI.

Reviews received from peers will be collated and forwarded to applicants. Applicants will then be afforded the opportunity to submit a response (*2 page max.*) to reviewers' comments. Applicants will be given a defined period of time in which to respond (*forward notice of dates will be indicated to applicants*).

Reviewers will score all applications based on the same review criteria used for assessment of pre-proposals:

Strength of translational element and strategic relevance

- Fit with the objectives and scope of the call
- The suitability of the development strategy
- Medical need and potential impact on healthcare
- The anticipated outputs, outcomes (e.g. patents), potential payback, impacts of the proposed research and competitive advantage
- Value for money

Scientific quality and innovation

- Clarity of the research question
- The background to the proposed research, justifying the need for work in this area, drawing particularly on existing evidence

- Completeness of the literature review and relevance to study design/research plan
- Clarity of rationale for the research approach and methodology
- Appropriateness of the research design
- Appropriateness of the research methods
- Strength of supporting preliminary data
- Anticipation of difficulties that may be encountered in the research and plans for management
- Originality of the proposed research in terms of hypotheses/research questions addressed, novel technology/methodology and or novel applications of current technology/methodology
- Potential for the creation of new or advancement of knowledge and evidence of benefit to the area covered by the research

Expertise and research environment

- Qualifications of the applicants, including training, experience and independence (relative to career stage)
- Experience of the applicants in the proposed area of research and with the proposed methodology
- Expertise of the applicants, as demonstrated by scientific productivity over the past five years (publications, books, grants held, etc.). Productivity should be considered in the context of the norms for the research area, applicant experience and total research funding of the applicant
- Track record of applicants as demonstrated by the outputs, outcomes and impacts on the health of patients and/or the public arising from previous grants
- Ability to successfully and appropriately develop research findings
- Quality of the plan for using and disseminating the knowledge, potential for promoting innovation and clear plans for the management of intellectual property, where appropriate, to ensure optimal use of the project results for the patient and the healthcare system
- Appropriateness of the team of applicants to carry out the proposed research, in terms of complementarity of expertise and synergistic potential
- Availability and accessibility of suitably qualified personnel, facilities and infrastructure required to conduct the research
- Project management group membership and experience
- Suitability of the environment to conduct the proposed research

Milestones and Deliverables

- Project management plan with clear and realistic milestones and deliverables
- Clearly stated, quantified target values that will be used to measure whether a milestone has been reached
- Availability of the appropriate resources, such as team members and infrastructure, required to meet milestones
- Suitable risk management plan

10.2.2 Stage 2 (Committee Review)

All full applications will proceed to Stage 2 of the review process. A Committee as per Stage 1 will be convened. In addition to briefing material, committee members will receive the original application, international expert reviews and the applicant's response to reviewers' comments. Committee members will assess the inputs of the international peer reviews and the overall merit and priority of applications for the advancement of the treatment and prevention of human disease. Committees will be invited to rank proposals and to make recommendations for applications to be approved for further consideration by the HRB-SFI. When ranking proposals, committee members will give due regard to the applicant's career stage and budget requested.

During Stage 2: In addition to the criteria outlined above, the Review Committees and the HRB-SFI will also consider:

- *The applicant's record in securing non-exchequer funding (commensurate with career stage)*
- *The scientific and strategic merits of other proposals within the overall context of the HRB and SFI missions*
- *The availability of current and future funds and value for money*

An executive committee from both funding agencies will agree on the final ranking prior to submitting to Boards for approval.

The HRB-SFI reserves the right to carry out pre-award site visits by international peers where required. Pre-award site visits conducted by HRB and/or SFI staff to examine infrastructure will also occur, where appropriate. Performance of applicants on previous HRB and SFI awards, as determined through site visits and/or annual reports, will be taken into consideration in the decision-making process. *The final funding decisions are at the sole and exclusive discretion of the HRB-SFI.*

The identity of experts who conduct both the external and committee review shall remain confidential and shall not be disclosed to the applicants. However, decisions resulting from the evaluation will be given to the applicant, including all of the external reviews (after Stage 1) and further committee comments, if appropriate, following the conclusion of the HRB-SFI review process.

Reviewers are required to respect the confidentiality of the peer review process, which is designed to protect and preserve the integrity of the HRB-SFI's advisers and processes. Reviewers may not discuss any aspect of the scoring or assessment with applicants or colleagues. The HRB-SFI shall not be liable for the release of information concerning proposals to third parties by those international scientists involved in the merit review process.

The HRB-SFI reserves the right to modify the review process. Applicants will be notified of any relevant modification to the review procedure.

10.3 Conflict of interest

Conflict of interest rules *are applied rigorously*. Where a conflict of interest exists, the reviewer is requested to inform the HRB-SFI immediately so that an alternative reviewer may be appointed. International peer reviewers will not provide comments or scores on any application on which they have a conflict of interest.

Reviewers must adhere to high standards of integrity during the peer review process. They must respect the intellectual property of applicants and may not appropriate and use as their own, or disclose to any third party, ideas, concepts or data contained in the applications they review.

A disqualifying conflict of interest may exist if a peer reviewer:

- Was involved in the preparation of the application
- Stands to benefit directly should the proposal be accepted or rejected
- Is in some way related to the Principal Investigator at a personal or professional level
- Is a former supervisor of the Principal Investigator
- Is a collaborator of the Principal Investigator (up to 10 years previously)

A potential conflict of interest may exist in some cases, which is not covered by the disqualifying conflict of interest rules indicated above.

11. Timeframe

4 March 2011	Opening of call
14 April 2011	Deadline for pre-proposal submission.
21 April 2011	Deadline for Signature Page submission.
July 2011	Committee Meetings will take place in June 2011 with a view to progressing 10-12 applications to the full application stage by mid-end of July 2011.
August 2011	Deadline for Full proposal submission.
September 2011	Deadline for Signature Page submission.
March 2012	Committee Meetings will take place in early February 2012 with a view to making recommendations to the Board of the HRB-SFI in March 2012. All applicants will be notified following Board approval of recommendations.
April 2012	Contracts will be issued from April 2012 with a view to beginning the research project in mid 2012.

12. Contacts

For further information on the Translational Research Awards contact:

Dr Catherine Gill

Project Officer
Health Research Board
73 Lower Baggot Street
Email: cgill@hrb.ie
Tel: +353 1 2345188

Dr Siobhan Roche

Scientific Programme Manager
Life Sciences Directorate
Science Foundation Ireland
Email: TRA@sfi.ie

Queries regarding the general principles and scope of the call can be directed to either the HRB or SFI. For queries relating to the administration of the call and eGrants please contact the HRB only.

The HRB-SFI reserves the right to reject any application that does not meet the terms of this call. The decision of the HRB-SFI Board in respect of any grant application is final and cannot be appealed or reviewed.

Appendix I - Definitions of Strategic Areas

Patient-Oriented Research Applications submitted under this category should have the patient at the centre of the research goals and generate clinically relevant results. Defined as research conducted with human subjects, or on material of human origin such as tissues, specimens and cognitive phenomena. Projects in this space often include components of applied biomedical work and or/components of health services research in addition to clinical research. Research studies involving *in vivo* or other appropriate pre-clinical models are eligible, as are computational or bio-informatics studies with an emphasis on yielding clinically relevant results. Research should focus on (i) mechanisms of human disease (ii) therapeutic interventions (iii) clinical trials⁶ (iv) use of new technologies for the diagnosis, treatment and prevention of disease (v) emotional, social, behavioural and developmental mechanisms of health and disease.

Applications that fall into the category of 'mechanisms of human disease' in relation to Patient-Oriented Research will only be considered in the context of translational research, as defined for this scheme. As such, applicants will have already identified targets (or disease processes) of interest which underpin their particular 'disease mechanism' and 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.

Medical Devices A medical device is a product which is used for medical purposes in patients, in diagnosis, therapy or surgery. Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings.

Diagnostics Products used for the diagnosis of disease or medical condition.

E-health Healthcare practice which is supported by electronic processes and communication including services such as electronic health records, telemedicine, consumer health informatics, health knowledge management, virtual healthcare teams, e-health grids, and health information systems. Examples of such research include the development of electronic patient records, development of technology and/or software to support remote patient monitoring and physiological body sensors and development of algorithms/software to enable characterisation of disease from medical images.

⁶ Studies involving early phase First-in-man to Phase I clinical trials are eligible under this scheme, however, later phase trials are outside the scope of the scheme – see Translational Continuum, Appendix II.

Appendix II Translational Continuum

