



US-Ireland R&D Partnership Programme

Guidance for ROI and NI applicants for Submission of Tri-Partite Proposals to the National Institutes of Health (NIH)

Version: 13 March 2019

Close-to-final draft Tri-Partite Proposal **DEADLINE** – at least **6 weeks** in advance of NIH deadline or, *if applicable*, the deadline at the US University's Research Office in advance of the NIH submission deadline

Mandatory 'Intention to submit' form required **at least 10 weeks** in advance of the full submission deadline at NIH

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1. BACKGROUND AND OBJECTIVES

The US-Ireland Research and Development Partnership, launched in July 2006, is a unique initiative involving multiple funding agencies across three jurisdictions: United States of America, Republic of Ireland & Northern Ireland.

The overall goal of the Partnership is to increase the level of collaborative R&D amongst researchers and industry professionals across the three jurisdictions. This collaboration aims to generate valuable discoveries and innovations which are transferable to the marketplace, or will lead to enhancements in population health, disease prevention or healthcare.

The Partnership achieves its goals through tri-partite research projects in which the funding agencies fund the elements of research undertaken in their own jurisdiction. Importantly, the Partnership must add significant value to each research programme above that achievable by the PI in each jurisdiction working alone.

The current focus of the US-Ireland R&D Partnership Programme, as agreed by the **Partnership Steering Group**, is on the following six thematic areas:

- Sensors & Sensor Networks
- Nanoscale Science and Engineering
- Telecommunications
- Energy & Sustainability
- Health
- Agriculture

This guidance document outlines the objectives, eligibility, funding available, review process and application procedures for submission of a US-Ireland R&D Partnership proposal to the **National Institutes of Health (NIH)**. This covers the Health theme but may also include projects related to the use of sensors and/or nanotechnology in health which are relevant to some NIH funding calls.

For proposal submissions to the **National Science Foundation (NSF)**, please refer to the US-Ireland R&D Partnership programme guidance for RoI and NI applicants for Submission of Tri-Partite Proposals to *the National Science Foundation (NSF)* on the SFI website – [US-Ireland R&D Partnership programme](#).

For proposal submissions under the **Agriculture theme** to the **National Institute of Food and Agriculture [NIFA (US)]**, please contact the Department of Agriculture, Food and the Marine [DAFM (RoI)] or Department of Agriculture, Environment and Rural Affairs [DAERA (NI)]. Further details on the Agriculture theme can be accessed from the webpage of the [Department of Agriculture, Food and the Marine](#).

1.1 PARTNER AGENCIES

The Partner Agencies are the bodies in each jurisdiction that have agreed to provide research funding depending on the thematic research area. For applications under the **Health** theme, these include the following:

- In the **US**, the partner agency is the **National Institutes of Health (NIH)**¹. The NIH consists of multiple agencies which offer a number of calls for proposals
- In the **Republic of Ireland (RoI)**, the partner agencies are **Science Foundation Ireland (SFI)**²; and the **Health Research Board (HRB)**³
- In the **Northern Ireland (NI)**, the partner agencies are the **Health & Social Care R&D Division (HSC R&D)**⁴*, the **Department for the Economy (DfE)**⁵, and **Invest Northern Ireland (InvestNI)**⁶.

**HSC R&D Division have in place an arrangement with the Medical Research Council (MRC) to co-fund the NI element of a number of the successful health related US Ireland Awards*

The US-Ireland R&D Partnership is guided by a Steering Group comprised of high-level representatives from the three jurisdictions. The function of the Steering Group is to oversee the strategic and operational aspects of the Partnership and to guide, monitor and evaluate the collaborative efforts. The Steering Group is supported by a Secretariat, provided by [InterTradeIreland](#), the cross-border business development body.

2. REMIT AREA

The remit of the US-Ireland R&D Partnership programme was expanded in 2017 to cover the remit of the National Institutes of Health due to the partnership nature of the programme. For further information on the remit of individual Institutes, please visit the following link: <https://www.nih.gov/institutes-nih>

Please note however that the following will be **not** be considered for funding by RoI and NI funding agencies under this programme:

- Applications from individuals applying for, holding, or employed under a research grant from the tobacco industry
- 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

Grants supported under this programme are typically **R01 or equivalent Research Project**

¹ National Institutes of Health (<http://grants.nih.gov/grants/oer.htm>)

² Science Foundation Ireland (<http://www.sfi.ie/>)

³ Health Research Board (<http://www.hrb.ie/>)

⁴ HSC R&D (<http://www.research.hscni.net/>)

⁵ Dept of the Economy (<https://www.economy-ni.gov.uk/>)

⁶ Invest NI (<http://www.investni.com/>)

Grants. Please ensure that the research topic of the US-Ireland proposal satisfies NIH funding requirements. The US partner is strongly advised to seek advice from appropriate scientific programme staff at the target NIH Institute or Centre to discuss the relevance and/or focus of the proposed research before submitting an application.

3. HOW THE PROGRAMME OPERATES

Each US-Ireland R&D Partnership proposal must have a minimum of one applicant from each jurisdiction and significant research participation by all three jurisdictions. The work proposed for each jurisdiction must add significant value, so that the overall programme of research goes beyond what might be achieved by any one PI working alone supported by national funding only.

The applicants from each jurisdiction will write a joint “tri-partite” proposal typically in the R01 format required by NIH. It is the responsibility of the US partner to submit the tri-partite proposal to the NIH for review. Proposals are evaluated in accordance with the standard NIH merit review criteria of intellectual merit and broader impacts of the proposed effort. The funding agencies on the island of Ireland in the RoI and NI have agreed to accept the decisions of NIH with regard to the suitability for funding of individual proposals.

In the **RoI**, the funding agencies, the Health Research Board (HRB) and Science Foundation Ireland (SFI) operate a rotating administration of the scheme. Either the HRB or SFI will act as the lead contact and route for communication with the applicant. Both websites will indicate the correct point of contact at any given time.

In **NI**, the Health & Social Care R&D Division (HSC R&D) administer the scheme. HSC R&D reserves the right to discuss applications with DfE and InvestNI and other US-Ireland partner agencies regarding shared funding opportunities.

The following requirements relate only to applicants/co-applicants in the Republic of Ireland and Northern Ireland for their respective funding agencies and are not required by the NIH for US applicants.

(i) Notification of Intent to Submit

In order to participate in a US-Ireland R&D Partnership proposal to the NIH, NI and RoI applicants who are eligible (*please see Section 5 regarding eligibility requirements*) must each send a **mandatory** “Intention to Submit” form to their relevant funding agency, from the Research Institution Research Office on behalf of the RoI or NI lead applicant. The associated short form must be submitted **at least 10 weeks** in advance of the full proposal deadline at NIH.

The information required is listed below and the form can be found at **Appendix 1**.

- Name and Research Institution of the RoI, NI and US applicants
- Information regarding the eligibility of the RoI and NI applicants

- US Target Institute/Centre, Target programme/FOA/call, submission deadline⁷
- Proposed topic, title of proposal, abstract
- Information regarding the expertise and expected budget request for each jurisdiction

For RoI applicants, please submit to USIreland@sfi.ie

For NI applicants, please submit to USIreland@hscni.net

The information in this form will be used for planning purposes by the agencies. **It is important to note that draft full proposals (see section (ii)) will not be accepted if the “Intention to Submit” form has not been submitted within the specified timeframe.**

(ii) Draft “Tri-Partite” proposal submission

A close-to-final draft of the “tri-partite” full proposal for submission to the NIH, (typically R01 or equivalent Research Project Grant programme) in NIH format, must be submitted to the RoI and NI funding agencies **at least 6 weeks** in advance of the NIH deadline, or if applicable, the deadline at the US University’s Research Office in advance of the NSF submission deadline. (Please refer to Section 7 - below for details).

Following submission of the draft proposal, the funding agencies *will assess the proposal in order to*

- a) determine if there is evidence of significant participation by all partners,*
- b) to pre-approve the budget for the project, and if supportive c) to inform the relevant personnel at the NIH of the RoI/NI support for the proposal should it be approved for funding, and d) to provide a Funding Commitment Letter to the applicant for inclusion in the full proposal submission to NIH.*

Detail on the level of support available from each funding agency is outlined in Section 6 – Funding.

4. ELIGIBILITY OF RESEARCH INSTITUTIONS

The Research Institution⁸ is the institution in charge of the financial and administrative co-ordination of the research project receiving a research grant from a partner. Research Institutions must be situated in the Republic of Ireland or Northern Ireland.

Applications must come from eligible Research Institutions. **Appendix 2** includes a list of eligible Research Institutions in the RoI and NI who may apply to NIH under the US-Ireland R&D Partnership programme. If your Research Institution is not listed, please contact

⁷ If an applicant wishes to submit to a non-standard R01 deadline they must indicate this on their Intention to Submit, and provide written confirmation of the non-standard deadline

⁸ The term ‘Research Institution’ refers to those eligible under both the HRB Host Institutions and the SFI Research Bodies policies, as well as the eligible Northern Ireland institutions

USIreland@sfi.ie prior to submission.

5. ELIGIBILITY CRITERIA

5.1 Eligibility Criteria for Republic of Ireland Applicants

(i) Applicant contract status

The lead applicant (and co-applicant/s) must be:

- (i) A member of the academic staff of an eligible Research Institution (permanent or with a contract that covers the period of the award), or
- (ii) A contract researcher with a contract that covers the period of the award, who is recognised by the Research Institution as an independent investigator and will have an independent office and research space at the host Research Institution for which he/she will be fully responsible for *at least* the duration of the US-Ireland R&D partnership programme award.
- (iii) An individual who will be recognised by the Research Institution upon receipt of the US Ireland R&D partnership programme award as a member of the academic staff or as a contract researcher as defined above. The applicant does not necessarily need to be employed by the Research Institution at the time of proposal submission.

Research Institution submission confirms that the lead applicant (and co-applicant/s) meets these criteria and is either a member of the academic staff, a contract researcher, or awaiting appointment as defined above. A co-applicant may be located at a different eligible Irish Research Institution than the lead applicant. In this case, the grant will be administered through the Research Institution of the lead applicant only. A co-applicant, where applicable, must comply with the same eligibility and evaluation criteria as the lead applicant.

(ii) Applicant Track Record

The applicant must hold, or have held, either an SFI or HRB research award (*) **as either lead Principal Investigator (PI) or co-PI.**

()Research awards include but are not limited to SFI IvP, SFI PI, SFI RFP, SFI SRC, SFI CSET, SFI Research Professor, SFI PIYRA, SFI SIRG, SFI CDA, SFI President of Ireland Future Research Leaders award, SFI Charles Parsons, SFI Mathematics Initiative, US-Ireland R&D Partnership award, SFI Research Centre, Royal Society-Science Foundation Ireland University Research Fellowship, HRB-SFI Translational Research Awards, HRB HRA (as PI), HRB ILP (as PI), HRB CARG (as PI), HRB Emerging Investigator Award EIA (as PI), HRB Clinical Research Facilities, HRB Clinician Scientist Awards, HRB Research Leader Awards, HRB Clinical Trial Network, HRB Health Research Centre, HRB ICE (as PI), HRB Trials Methodology Research Network, or Imaging awards. Grants such as personal fellowships or travel grants are not included. If you are unsure as to whether your SFI/HRB award is considered eligible, please contact the relevant agency in*

advance of your submission.

- If the applicant is not an SFI or HRB awardee, s/he is expected to have demonstrated research independence through securing at least one independent research grant as lead investigator or as co-investigator. The grant must have been competitively awarded and internationally and independently peer reviewed. Eligible research grants would be expected to support at least one full-time equivalent, excluding the applicant(s), and include research team costs (e.g., materials and consumables). This EXCLUDES smaller awards such as travel grants, equipment grants, post-graduate fellowships, postdoctoral fellowships, and awards of short duration (12 months or less). Laboratory fit-out / setup funding, awards from the applicant's institution, and awards that have not been subject to external international peer review are also excluded.
- The applicant and any co-applicant(s) must have held a PhD or equivalent qualification⁹ for at least **five years** by the proposal deadline. *Applicants holding an equivalent qualification may be eligible but should nevertheless seek approval from SFI/HRB in advance of submitting a proposal.*
- US-Ireland partner agencies will not accept a second application whilst the first application is under review.
- If an applicant/co-applicant has been successful in securing a US-Ireland R&D Partnership award, they will not be entitled to apply for a subsequent award until at least the last 18 months of their active award.

5.2 Eligibility Criteria for Northern Ireland Applicants

(i) Applicant contract status

The lead applicant (and co-applicant/s) must be:

- a. A member of the clinical or academic staff of an eligible Research Institution (permanent or with a contract that covers the period of the award), or
- b. A contract researcher with a contract that covers the period of the award, who is recognised by the Research Institution as an independent investigator and will have an independent office and research space at the host Research Institutions for which he/she will be fully responsible for *at least* the duration of the US-Ireland R&D partnership programme award.

Research Institution submission confirms that the lead applicant (and co-applicant/s) meets these criteria and is either a member of the academic staff, or a contract researcher. A co-applicant may be located at a different eligible Northern Irish research institution than the lead applicant. In this case, the grant will be administered through the Research institution of the lead applicant only. A co-applicant, where applicable, must comply with the same eligibility

⁹ <http://www.sfi.ie/funding/sfi-policies-and-guidance/eligibility-related-information/index.xml>

and evaluation criteria as the lead applicant.

(ii) Applicant Track Record

- Applicants and any co-applicant(s) must have held a PhD for at least five years by the proposal deadline¹⁰.
- Applicants must have a track record of substantial research funding which demonstrates research independence¹¹. It is expected that they will have secured at least one independent research grant in the region of £200K as lead investigator (Chief Investigator). The grant must have been competitively awarded and internationally peer reviewed from a major research funder, e.g. UK Research Council or Health
- Department (including HSC R&D itself), NIH, prestigious national or international charity, e.g. Wellcome Trust, Cancer Research-UK, Diabetes UK. Eligible research grants would be expected to support at least one full-time equivalent, excluding the applicant(s), and include research team costs (e.g., materials and consumables). This excludes smaller awards such as travel grants, equipment grants, post-graduate fellowships, postdoctoral fellowships, and awards of short duration (12 months or less). Laboratory fit-out / setup funding, awards from the applicant's institution, and awards that have not been subject to external international peer review are also excluded.
- US-Ireland partner agencies will not usually accept a second application whilst the first application is under review. (NI applicants may contact HSC R&D Division regarding this criterion)
- If an applicant/co-applicant has been successful in securing a US-Ireland R&D Partnership award, they will not usually be entitled to apply for a second award until the last 18 months of their active award. (NI applicants may contact HSC R&D Division regarding this criterion)

6. FUNDING

The NI and RoI funding agencies have their own specific funding streams available for researchers in NI and RoI applying to the US-Ireland R&D Partnership programme.

¹⁰The official date of a PhD is defined as the year that the degree was conferred (i.e. the year printed on the official PhD certificate). The number of years is determined by calendar year. Therefore, only individuals with an official date of 2014 or earlier are eligible to apply in 2019 for example

¹¹ Defined as being able to demonstrate a leading role in the construction (writing and negotiating) of successful national or multinational collaborative grants and leading responsibility for grant management and supervision of a research team, building capacity, expertise and partnerships. Lead applicants from a university are normally expected to be at least at senior lecturer level.

6.1 SFI and HRB Funding

HRB and SFI are the funding agencies in the Republic of Ireland involved in the Health theme of the US-Ireland R&D Partnership programme. The agencies operate in partnership for this programme and each contribute 50% to funding the research costs of the RoI partners on any US-Ireland Health proposals approved for funding at the NIH.

RoI applicants may apply to RoI funding partners, SFI and HRB, for direct costs of up to €700K for a 3-5 year duration project. In addition to the direct costs, SFI and HRB also make an indirect, or overhead, contribution to the host research institution, which is reflected as 30% of the Direct costs, excluding equipment costs, and should not be included in the budget request.

Eligible costs are: Staff, running costs including materials and consumables, equipment and, travel and dissemination costs. One single budget template (**Appendix 3**) should be completed by the RoI partner(s) and each line item should be fully detailed and justified in the budget justification (max. 3 pages). Applicants should follow the budget guidelines provided in **Appendix 4** when completing their budget. The overhead should not be included in the RoI budget request.

6.2 HSC R&D Funding

NI applicants may apply to HSC R&D for maximum costs of up to £500k for a 3-5-year duration project, calculated as 80% of the Full Economic Cost (FEC). It is expected that HSC R&D costs will not exceed £130K in any one year. One single budget template (**Appendix 5**) should be completed by the NI partner and each line item should be fully detailed and justified in the budget justification (3 pages max.). Applicants should follow the budget guidelines for NI applicants provided in **Appendix 6** when completing their budget.

7. SUBMISSION OF DRAFT TRI-PARTITE PROPOSAL TO IRISH FUNDING AGENCIES

In advance of submission of the final tri-partite proposal to the NIH, the funding agencies in NI and the RoI will evaluate the close-to-final draft proposal and either approve or decline support. A close-to-final draft of the “tri-partite” proposal to the NIH must therefore be submitted to the NI and RoI funding agencies **at least 6 weeks in advance of the NIH submission deadline**, or *if applicable*, the deadline at the US University’s Research Office in advance of the NIH submission deadline.

Draft proposals will only be accepted from applicants who have submitted an Intention to Submit form no later than 10 weeks in advance of the NIH submission deadline.

Applicants should prepare their tri-partite proposal based on the guidelines and criteria outlined in the relevant NIH programme call and associated documentation.

To be deemed eligible for funding, a minimum of one applicant from each jurisdiction – NI, US,

and RoI - must be named on the proposal.

The RoI and NI funding agencies will accept a draft version of the tri-partite proposal **in NIH format**; however, the following sections/documents must be included in order for the agencies to accurately and fairly assess the level of support required:

- (i) A detailed overview of the research programme including a breakdown of the workpackages and tasks to be undertaken by partners in each jurisdiction
- (ii) CVs of each applicant in each jurisdiction in NIH format
- (iii) Copies of the requested budget in each jurisdiction
 1. For RoI applicants, details of the budget requested (using budget template provided in **Appendix 3**)
 2. For NI applicants, details of the budget requested (using HSC R&D budget template provided in **Appendix 5**)
 3. US applicant should use the standard NIH budget template
- (iv) Budget justification for the funding requested by RoI and NI partners (max. 3 pages for each jurisdiction)
- (v) For RoI applicants, a standard SFI/HRB coversheet signed by the applicant and approved by the appropriate signatory from their institution; please refer to **Appendix 7**.
- (vi) For NI applicants, a standard coversheet signed by the applicant and approved by the appropriate signatory from their institution; please refer to **Appendix 8**.
- (vii) An **'added value' appendix** (1 page) which includes an outline of how the work proposed for each jurisdiction adds significant value so that the overall programme of research goes beyond what might be achieved by any one PI working alone supported only by national funding
- (viii) If a Gantt chart or equivalent has not been included in the draft application, it should be included in the appendix
- (ix) **Multi-applicant Management & Communication Plan** - please include a section where it clearly outlines how the multi-applicant team will manage the programme. It is advisable that you refer to regular conference calls or annual team meetings, for example, or other methods of communication that you expect to use to enable the efficient management and a successful outcome of the proposed partnership project
- (x) Section stating ethical/regulatory approvals required and inclusion of Letters of Support from Clinical Trial Sponsors where appropriate (see Section 8 below)
- (xi) Confirmation that the proposal does **not involve**: (a) applications from individuals applying for, holding, or employed under a research grant from the tobacco industry OR (b) 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
- (xii) RoI applicants are asked to provide specific details where they have access to, or plan to

access, the support/services of a Research Infrastructure (e.g. CRF/C, biobank, SFI-funded infrastructure) for the project. The following information must be provided in the form provided in **Appendix 9**:

- Name and address of the Research Infrastructure
- Information on the nature and stage/s of the input/advice/collaboration/service
- Information on the costs of providing the service/input including reference to access charges where applicable, setting out where this is provided in-kind, from additional funding or requested from the project budget
- Rationale for the choice of facility/centre/equipment Evidence of this support/service must be provided with the draft Tri-Partite proposal **in the form of a completed Infrastructure Agreement Form** signed by the Director of the Facility/Centre.

All documents must be combined into a single Adobe pdf document and emailed to USIreland@sfi.ie for RoI applicants, and USIreland@hscni.net for NI applicants. Please note that only the signature page should be scanned, electronic signatures are also acceptable.

8. ETHICAL ISSUES

For RoI applicants

RoI investigators and research institutions must ensure that, before the research commences and during the full award period, all the necessary ethical, legal and regulatory requirements in order to conduct the research are met, and all the necessary licences and approvals have been obtained. All Research Institutions are responsible for ensuring that a safe working environment is provided for all individuals associated with a research project.

[SFI Policies and Positions](#) and Guidance on Ethical and Scientific Issues can be found [here](#).

Ethical and Regulatory Approvals

Ethical approval is required for all research funded in RoI that involves human participants, human material (including tissue) or animals. In addition, Clinical Trial Approval from the Health Products Regulatory Authority is required for trials involving medicinal products/medical devices within the RoI. Necessary authorisations for trials involving medical devices differ depending on the device. Applicants are responsible for ensuring that all necessary approvals are in place prior to the start of the research.

Applicants should allow sufficient time to obtain ethical and/or competent authority approval and/or animal licenses as a copy of any of these approvals must be submitted to the Lead Agency before the initiation of the research involving animal and/or human subjects. It is suggested that these are sought in parallel to the submission of the application to the NIH.

In cases where such research may not commence until a later stage of an award, submission of ethical and regulatory approvals may be permitted following the award start date but prior to commencement of the research involving animal and/or human subjects.

Sponsorship for Clinical Trial Applications

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, HRB/SFI *cannot take on the role of sponsor*. Plans for appropriate sponsorship arrangements must be included in the draft application i.e. Letters of Support must be provided from sponsors or potential sponsors.

For NI applicants

For all Awards offered by HSC R&D Division, the Award Holder and Host Research Organisation will agree to uphold the Public Health Agency, HSC R&D Division Terms and Conditions of Awards. <https://research.hscni.net/terms-and-conditions-awards> HSC R&D Division must ensure that research projects have a research Sponsor and assumes that if HSC Research Governance permission and/or favourable ethical opinion from an HSC Research Ethics Committee are required then these will be in place prior to the start of the research. A determination should be made as to whether a Clinical Trial Authorisation is required; MHRA advice may need to be sought.

9. TRI-PARTITE DRAFT PROPOSAL - REVIEW PROCESS & CRITERIA

Each agency will review the draft tri-partite proposal based on the following criteria:

- Evidence of significant participation by all partners
- The budget is well-justified and represents value for money.
- The work proposed for each jurisdiction adds significant value so that the overall programme of research goes beyond what might be achieved by any one applicant working alone supported only by national funding.
- The overall quality of the proposal.

The final decision on the scientific merit of the tri-partite proposal lies with the NIH peer review process.

10. SUBMISSION OF FINAL TRI-PARTITE PROPOSAL TO NIH

Once support of the close-to-final draft proposal has been approved by the RoI and NI funding agencies, the RoI and NI applicants are permitted to submit the tri-partite proposal to the NIH via their US partner, as it is the US partner who takes the lead on submission of the full proposal to the NIH via their Research Institution.

Each of the RoI and NI funding agencies will issue a Funding Commitment Letter outlining their level of budget commitment subject to NIH approval of the tri-jurisdictional proposal. Funding Commitment Letters are sent to the applicant by their funding agency and **must** be included in

the final NIH submission.

SFI/HRB will issue a single Funding Commitment Letter to the RoI applicant, who is responsible for ensuring its inclusion in the final proposal submission to the NIH. HSC R&D will issue a Funding Commitment Letter to the Northern Ireland applicant whose responsibility it is to provide this to the US partner for inclusion in the final proposal submission to the NIH. These Funding Commitment Letters are sent to the NIH by SFI/HRB to inform them of the support of the overseas collaborators by their funding agencies should the application be approved for funding by the NIH.

The US partner will be responsible for submitting the final proposal including the Funding Commitment Letters to the NIH via their institution.

A copy of the final NIH version of the submitted proposal along with NIH FastLane submission code **must** be sent to the relevant funding agencies by the applicants within two weeks of the NIH submission deadline.

For additional guidance on full proposal submission please see [FAQs](#).

11. POST-AWARD REVIEW

Republic of Ireland-based applicants receiving funding from SFI and HRB will be subject to reporting requirements to the RoI funders. These will include, but are not limited to regular reporting such as an annual report on progress, researcher census, an end of grant report, participation in interim reviews and other reporting as requested such as a contribution to SFI's Researcher snapshots¹². The Lead agency will manage post-award monitoring and full details of requirements for the post-award management of awards will be set out within the Grant General Terms and Conditions.

SFI/HRB Post Award requirements must be adhered to, that is, those **awardees that fail to comply will risk having their grant payments suspended and/or the processing of any applications under review in other SFI and HRB calls paused**, until their reporting status is rectified.

As is the case for all awards, SFI and HRB reserve the right to assess progress during the lifetime of awards made under the auspices of the Partnership. *HRB/SFI reserves the right to terminate a grant if, in the reasonable opinion of the funding agency, progress is not deemed to be satisfactory.*

Northern Ireland-based applicants receiving funding from HSC R&D will be subject to reporting requirements of HSC R&D Division. These will include, but are not limited to regular reporting such as an annual report on progress, completion of Project Management Plan and research outputs, a final report and other reporting as requested.

The full details of requirements for the post-award management of awards will be set out within

¹² <https://www.sfi.ie/funding/award-management/reporting-procedures/>

the Terms and Conditions of the Award.

For further information, ROI applicants should contact USIreland@sfi.ie and NI applicants should contact USIreland@hscni.net

PLEASE NOTE: Awardees must adhere to and comply with the grant General Terms and Conditions of the relevant funding agency who will govern the administration of the award, as detailed in the corresponding award letter.

12. GDPR statements

12.1 SFI Statement

The General Data Protection Regulation¹³ is a legal framework that sets out guidelines for the collection and processing of personal information of individuals within the European Union¹⁴. Applicants are advised that they must be compliant with this regulation if they collect or process personal data.

SFI may collect, use and disclose personal data provided in the application and/or otherwise obtained under, or in connection with, the application for processing the submission, for the performance of its statutory powers and functions, and for the general activities of SFI. Further details regarding SFI's collection, use and disclosure of personal data, and the rights of individuals with respect to any personal data held by SFI, are available in the SFI Privacy Statement¹⁵.

During peer-review procedures, information may be sent to external experts in countries outside of the European Economic Area, including countries that are not recognised by the European Commission as having adequate data protection laws. By submitting an application to SFI, the Research Body and members of the Research Team are agreeing that they consent to the processing and transfer of personal information in this way.

During the application process or at any time thereafter, SFI may contact the Research Body, the Principal Investigator, or any member of the Research Team with regard to funding opportunities, activities or events organised by SFI or other relevant bodies, or for the purposes of monitoring and evaluation (including, but not limited to, the collection of scientific data or data relating to the application process). SFI may choose to authorise a third party to contact the Research Body, the Principal Investigator or any member of the Research Team on its behalf.

12.2 HRB statement

By participating in the US Ireland Partnership Programme, you consent that HRB uses the information you provide (regarding all applicant team members) to process your application as described in these Guidance notes, contact you about your application, and if you are successful,

¹³ <https://www.dataprotection.ie/>

¹⁴ <https://eugdpr.org/>

¹⁵ <http://www.sfi.ie/privacy/>

to manage your grant throughout its lifetime in accordance with HRB general T&C for research awards. This will include contacting you with regard to monitoring of progress through written reporting and other means e.g. interim review. We will publish some basic information on successful awards including PI, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended we will continue to keep your information on file (in accordance with HRB policies) to allow us to evaluate the outcomes, outputs and impacts of HRB investment in your research.

Please note that we will also use information associated with unsuccessful applications for a number of the purposes outlined above such as generating general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment e.g. demographics of applicants, research areas of applicants. Similarly we will use the information provided about people employed on awards to help evaluate our career support and capacity building initiatives. Please see the HRB Privacy policy for further information <https://www.hrb.ie/about/legal/privacy-policy/>.

By participating in the US Ireland Partnership Programme, applicants understand that we will need to share information (e.g. their name, institution, project title, funding requested) with the NIH in order to confirm HRB, SFI, Health and Social Care NI support for their application (i.e. the submission of the Funding Commitment Letters).

12.3 HS R&D Division statement

Please see the HSC R&D Division Privacy notice:

<https://research.hscni.net/sites/default/files/Privacy%20Notice%20v0618.pdf>

APPENDIX 1 - MANDATORY INTENTION TO SUBMIT FORM

For RoI applicants, please complete the relevant sections and submit in the form of an Adobe pdf document to USIreland@sfi.ie

For Northern Ireland candidates, please complete the relevant sections and submit in the form of an Adobe pdf document to USIreland@hscni.net

This form must be submitted to the relevant funding agencies, North and South, via the Research Body Research Offices of the RoI and NI lead applicant respectively at least 10 weeks in advance of the full proposal deadline at NIH.

Section 1: Contact Details and eligibility* of applicants/co-applicants **Please**

insert another table as required if co-applicants exist

RoI Applicant Contact Details

Title	
Name	
Department	
Institution	
Telephone	
Email	
Eligibility:	<p>(i) Contract status</p> <p>(ii) Qualifying research award: awarding body, grant title, grant #, funding period</p> <p>(iii) Year PhD awarded</p> <p>(iv) If you currently hold a US-Ireland award, when did the award commence?</p>

NI Applicant Contact Details

Title	
Name	
Department	
Institution	
Telephone	
Email	
Eligibility	(i) Contract status

*Please review the eligibility criteria in Section 5 and provide details confirming the eligibility of the applicant and any co-applicants to apply to the US-Ireland R&D Partnership programme. This is **ONLY** required for the RoI and NI applicants/co-applicants and **NOT** for the US applicants.

	<p>(ii) Year PhD awarded</p> <p>(iii) Qualifying research award: awarding body, grant title, grant #, funding period</p> <p>(iv) If you currently hold a US-Ireland award, when did the award commence?</p>
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US Applicant Contact Details

Title	
Name	
Department	
Institution	
Address	
Telephone	
Email	
Eligibility	NOT REQUIRED

Submission by Research Office required to inform them about the submission and to confirm eligibility

Section 2: NIH INSTITUTE and PROGRAMME DETAILS

Target NIH Institute	
NIH Programme	
Submission Deadline	

Section 3: APPLICATION OVERVIEW

Proposed topic, title of proposal, abstract

Proposed Topic	
Title of proposal	
Abstract (max 250 words)	

RoI:	Highlight area of speciality which the RoI partner is contributing to the proposal	
	Indicative total direct costs likely to be requested for RoI	€
NI:	Highlight area of speciality which the NI partner is contributing to the proposal	
	Indicative total budget figure likely to be requested for NI	£
US:	Highlight area of speciality which the US partner is contributing to the proposal	
	Indicative total budget figure likely to be requested for US	\$

APPENDIX 2 - List of Eligible Research Institutions

Republic of Ireland

The following ROI Institutions are eligible to apply for funding under the US-Ireland R&D Partnership Programme, as they are both recognised *HRB Host Institutions* and *SFI Research Bodies*.

- Athlone Institute of Technology
- Cork Institute of Technology
- Dublin City University
- Institute of Technology, Sligo
- Dundalk Institute of Technology
- Limerick Institute of Technology
- National Cancer Registry Ireland
- National University of Ireland, Galway
- National University of Ireland, Maynooth (Maynooth University)
- Royal College of Surgeons in Ireland
- Teagasc
- The University of Dublin (Trinity College Dublin)
- TU Dublin
- University College Cork
- University College Dublin
- University of Limerick
- Waterford Institute of Technology

If your Research Institution is not listed, please contact USIreland@sfi.ie in advance of submission.

Northern Ireland

The following NI Institutions are eligible to apply for funding under the US R&D Partnership Programme.

- Queen's University Belfast <http://www.qub.ac.uk/>
- Ulster University <https://www.ulster.ac.uk/>
- Belfast Health and Social Care Trust <http://www.belfasttrust.hscni.net/>
- Northern Health and Social Care Trust <http://www.northerntrust.hscni.net/>
- South Eastern Health and Social Care Trust <http://www.setrust.hscni.net/>
- Southern Health and Social Care Trust <http://www.southerntrust.hscni.net/>
- Western Health and Social Care Trust <http://www.westerntrust.hscni.net/>

APPENDIX 3 - Budget Template for RoI Applicants



US-IRELAND R&D PARTNERSHIP PROGRAMME BUDGET TEMPLATE FOR REPUBLIC OF IRELAND APPLICATIONS

Maximum allowable RoI Budget Request is €700k

Overheads of 30% of direct costs, excluding equipment, will be applied at time of contract

See budget guidance in Appendix 4.

Total Proposed budget (in Euro)

Description	Year 1	Year 2	Year3	Year 4	Year 5	Total
Staff						
Equipment						
Running costs						
Dissemination						
TOTAL						

Proposed staff costs (in Euro) (Please include salary scale used and point on scale)

Description	Year 1	Year 2	Year3	Year 4	Year 5	Total
TOTAL						

Proposed Equipment costs (in Euro)

Description	Year 1	Year 2	Year3	Year 4	Year 5	Total
TOTAL						

Proposed Running costs (in Euro)

Description	Year 1	Year 2	Year3	Year 4	Year 5	Total
TOTAL						

Proposed Dissemination costs (in Euro)

Description	Year 1	Year 2	Year3	Year 4	Year 5	Total
TOTAL						

APPENDIX 4 - Budget guidance for RoI applicants

Please note that this budget guidance is specific **only** to applications being submitted to NIH under the US-Ireland R&D Partnership programme

1. Staff	Must be listed for each salaried personnel and include costs for 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 IUA website scales for the most up-to-date recommended salary scales for academic researchers https://www.iua.ie/download/73355/</p> <p>Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure.</p> <p>Please state the pay scale used and the level and point on the scale. This should be justified accordingly. For appointment of Research Fellows or Senior Research Fellows evidence of position must be provided at point of contract negotiation. Applicants can allow for annual, single-point salary scale point increases.</p> <p>Note: This scheme does not provide funding for the salary or benefits of applicants, co-applicants or collaborators within research institutions who are already in receipt of salary or benefits.</p>
b) Employer's PRSI	Employer's PRSI contribution is calculated at 10.95% of gross salary for 2019, and 11.05% for 2020.
c) Employer Pension Contribution	<p>Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution.</p> <p>If applicable, state the amount of employer contribution based on the pro rata salary used to calculate this for reference</p> <p>Exceptions apply 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</p>

	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 allowable student stipend is €18,500 per annum (tax exempt).
e) Student Fees	Fees for students registered for a higher degree. SFI/HRB make a contribution of €5,500 per annum to student fees Please note only personnel in receipt of a student stipend are eligible to receive a student fee contribution.
2. Equipment Costs	Funding for equipment can be included in this section, where appropriately justified. It is expected that equipment requests would not exceed €50,000. All costs must be inclusive of VAT, where applicable.
3. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, transcription costs etc. Travel for participants to allow them to carry out the research project should be included under this heading and must be fully detailed and justified in the budget justification Maintenance costs of animals are allowed as follows ¹⁶ Access to necessary special facilities or services which are not available in the host academic or clinical institutions e.g. statistics and methodological consultancy support, biobanking, Clinical Research Facility support, access charges for SFI-funded infrastructures, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form' upload (Appendix 9).

¹⁶ The maximum allowable per diem rates for the maintenance of the most common strains of small animals are: mice (€0.50), other laboratory rodents (€1) and rabbits (€2) All per diem rates are inclusive of VAT at the prevailing rate. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis

	<p>We do not expect applications for consultancy for research design and statistics support in excess of €15,000.</p> <p>Costs associated with involving members of the public or patients in your research e.g. consultation workshops, costs of participation in advisory groups, travel expenses etc. should be charged to running costs.</p> <p>Data management costs for the duration of the project should be charged to running costs.</p> <p>The following costs are ineligible and will not be funded: training courses/workshops for funded research personnel, inflationary increases, cost of electronic journals, contingency or miscellaneous costs, replacement teaching costs, clinical time buyout, entertainment costs, technology transfer or patent costs, legal fees, relocation costs, International collaborator research costs, or membership fees</p> <p>Note: Costs falling within the overhead contribution such as office space, software licenses not specific to the proposed work, waste disposal fees, contribution to the cost of gases etc should not be requested under running costs.</p>
<p>4. Dissemination Costs</p>	<p>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 as justified</p>

APPENDIX 5 - Budget Template for NI Applicants (HSC R&D)

US-IRELAND R&D PARTNERSHIP PROGRAMME BUDGET TEMPLATE FOR NORTHERN IRELAND APPLICATIONS

Cost Categories	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Staff (include employers costs) state grades of staff and whole-time equivalents						
Consumables						
Travel & Subsistence						
Personal and Public Involvement (PPI)						
Exceptional Items						
Indirect Rate						
Estate Rate (specify whether laboratory rate or deskbased rate)						
Grand Total 100%						
Grand Total 80% fEC						

APPENDIX 6 - Budget guidance for NI applicants

Organisation costs (Overheads, Indirect costs, Estate costs)	<p>These are a share of the resources that cannot be directly attributed to an individual research project by nature of their activities. E.g. support services such as libraries, HR, finance, maintenance, utility costs etc.</p> <p><i>Universities:</i> HSC R&D Division provide research awards on a full economic cost (fEC) basis. In most cases HSC R&D Division pay a fixed proportion of 80% of the total fEC of research projects with the institutions providing the balance.</p> <p><i>HSC Trusts and Voluntary Sector Organisations:</i> In most cases HSC R&D Division pay an agreed overhead on staff costs associated with the research.</p>
Salary costs	<p>Salary costs are estimates taken from the application form. Only actual salary costs, (including the employer’s contribution to superannuation, national insurance and normal increments) verified by HSC R&D Division will be paid for the number of sessions/hours devoted to the Research Award but excluding time spent on professional duties. Costs will not normally be increased to meet the cost of any staff promotion or re-grading. Costs will not normally be included to fund recruitment of staff to Research Organisations to work on funded projects.</p>
Research Expenses/ Consumables	<p>A contribution to research expenses incurred and claimed in a given financial year will be paid. This can include: consumables required for the research project; travel expenses relevant to the project (excluding costs associated with travel category); attendance at specific training courses and workshops. Claims for the HSC R&D Division contribution towards research expenses and travel costs will only be paid if the expenses are properly incurred in pursuance of the research training/project and upon receipt of claims certified to be correct by an authorised signatory from the Research Organisation Finance Directorate. Confirmation of expenditure on the Award is required on an annual basis. Procurement of equipment, consumables and services, including maintenance, must comply with all relevant national and EU legislation and the Research Organisation’s own financial policy and procedures. Accepted procurement best practice in the higher education and HSC sectors must be observed.</p>
Travel Costs:	<p>A contribution, to fees and/or travel and subsistence costs for attendance at conferences in order to disseminate research findings and build networks and collaborations.</p>
PPI Costs:	<p>Costs associated with public involvement for the purpose of the research project. Can include support for meetings to disseminate findings, reimbursement of expenses, training and/or mentorship for PPI reps. Please note the reimbursement guidelines for the HSC.</p>
Exceptional Items:	<p>Directly incurred costs which are separated out because HSC R&D Division will fund them at 100% of fEC rather than the standard 80%</p>

APPENDIX 7 - Cover Sheet for US-Ireland Proposal, Republic of Ireland applicants



PROGRAMME NAME US-Ireland R&D Partnership Programme	NIH PROGRAMME NAME and CLOSING DATE FOR APPLICATIONS	THEMATIC AREA (tick as relevant) <input type="checkbox"/> Health <input type="checkbox"/> Sensors & Sensor Networks <input type="checkbox"/> Nanoscale Science & Engineering
TITLE OF PROPOSAL (up to 30 words)		
NAME OF HOST ROI INSTITUTION	TITLE & FULL NAME OF LEAD REPUBLIC OF IRELAND APPLICANT	
ROI REQUESTED BUDGET DIRECT COSTS		
Ethical approval required? <input type="checkbox"/> Yes <input type="checkbox"/> No From:		
<p>Signatures below confirm acceptance and agreement with the SFI and HRB grants and awards Terms and Conditions, and that the institution ensures the applicant meets eligibility requirements, and that the project is in full agreement with all legal and regulatory matters governing research in Ireland, and no aspect of this project is already being funded from another source and all details provided are correct.</p>		
ROI INSTITUTIONAL SIGNATORY AUTHORITY Name (print): Position: Email: Correspondence Address: Signed: Date:	LEAD Republic of Ireland CONTACT Signed: Date:	

APPENDIX 8 - Cover Sheet for US-Ireland Proposal, NI applicants

PROGRAMME NAME US-Ireland R&D Partnership Programme	NIH PROGRAMME NAME and CLOSING DATE FOR APPLICATIONS	
TITLE OF PROPOSAL (up to 30 words)		
NAME OF HOST NI INSTITUTION (including the Department where the research will take place)	TITLE & FULL NAME OF LEAD NORTHERN IRELAND CONTACT	
HSC R&D REQUESTED BUDGET (80% fEC)		
Ethical approval sought? <input type="checkbox"/> Yes <input type="checkbox"/> No From:		
<p>Signatures below confirm acceptance and agreement with the HSC R&D Division awards Terms and Conditions, and that the institution ensures the applicant meets eligibility requirements, and that the project is in full agreement with all legal and regulatory matters governing research in Northern Ireland, and no aspect of this project is already being funded from another source and all details provided are correct.</p>		
LEAD Northern Ireland CONTACT <i>"I declare that the information on this application form and any other information given in support of this application is correct to the best of my belief"</i> Signed: _____ Date: _____		
NI INSTITUTIONAL SIGNATORY AUTHORITY - Head of Department <i>"I confirm that I have read this application and that, if awarded, the work will be accommodated in the named Department."</i> Name (print): _____ Position: _____ Email: _____ Correspondence Address: _____ Signed: _____ Date: _____	NI INSTITUTIONAL SIGNATORY AUTHORITY - Research Office <i>"I confirm that I have read this application and that, if awarded, the work will be accommodated in the named Department."</i> Name (print): _____ Position: _____ Email: _____ Correspondence Address: _____ Signed: _____ Date: _____	

APPENDIX 9 - Infrastructure Agreement Form, ROI applicants



US-Ireland R&D Partnership Programme: Infrastructure Agreement Form

This form should accompany the draft submission from the ROI partner in advance of submission to the National Institutes of Health (NIH)

Applicants must provide details where they have access to, or plan to access, the support/services of a Research Infrastructure (e.g. CRF/C, biobank, SFI-funded infrastructure) for the project. Where there is a need for support from multiple centres, a completed form must be submitted for each individual infrastructure.

Section 1: Proposal details

TITLE OF PROPOSAL (up to 30 words)

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TITLE & FULL NAME OF LEAD APPLICANT

--

Section 2: Details of the Research Infrastructure

Centre/Facility/Unit

Name, Institution, address and Infrastructure grant code (where funded by ROI funder)

--

Please describe the nature of the support provided to the applicant team from the Research Infrastructure

Please provide details with regard to:

- *the nature of the role provided by the Research Infrastructure (e.g. service, advisory, co-applicant or official collaborator)*
- *the nature of the support provided to the project (e.g. access to specialised equipment, study design, biostatistics advice, clinical data collection, data management, etc.)*
- *the feasibility and the timescale for the delivery of the support to the project*

(max 500 words)

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Section 3: Funding

Please provide details on any income or expenditure related to the project arising out of accessing the Research Infrastructure. *Please note that items of expenditure which are being requested from the award budget must also be added into the budget section on the application form as well as detailed below.*

Category	Cost of support (€)	Specify if 1,2 or 3 1. <i>In-kind Contribution</i> 2. <i>Funding requested from project</i> 3. <i>Funded leveraged by additional contribution</i>
e.g. access charges		
e.g. methodological support		
e.g. imaging fees		
e.g. set up fee for database		
e.g. Overheads*		

Please edit/extend table as necessary to include additional categories

* If an overhead contribution is requested as part of securing the services of the Research Infrastructure, it must be included within the overall overhead contribution to the project budget. It is responsibility of the Lead Applicant, the Host Institution and the Research Infrastructure provider to establish any sub-agreements as to how the overheads payment will be distributed in such a case.

Provide details and justification for all items listed in the table above (max 200 words)

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Section 4: Signatures

Lead Applicant

As the Lead Applicant I confirm, to the best of my knowledge, that the information provided is correct.

Name (BLOCK CAPITALS): _____

Signature: _____ Date: _____

Director or any other person authorised on behalf of the Research Infrastructure or equivalent to endorse this agreement

As Director of the Research Infrastructure or equivalent (insert position)
_____ I confirm, to the best of my knowledge, that the information provided is correct.

Name (BLOCK CAPITALS): _____

Signature: _____ Date: _____

The Infrastructure Agreement Form must be included with the draft tri-Partite Proposal to USIreland@sfi.ie . Forms must be completed, signed, dated. Electronic signatures are acceptable.