

FAQ US-Ireland R&D Partnership Programme Applications to National Institutes of Health

The guidance for this call was last updated March 2019. As of March 2019, SFI is administering the programme on behalf of HRB and SFI and all queries should be directed to USIreland@sfi.ie

N.B.: For applications outside the health theme, please refer to the guidance on the SFI website

GENERAL

1. What is the US-Ireland R&D Programme (NIH stream)?

This is a programme where applicants from the United States (US), Northern Ireland (NI) and the Republic of Ireland (RoI) collaborate to submit a single, joint "tri-partite" proposal in response to calls for proposals at the National Institutes of Health (NIH). There must be at least one applicant from each jurisdiction, with the US partner bearing responsibility for submission of the joint "tri-partite" proposal to their home agency, NIH. If approved for funding at NIH, the partner agencies in RoI fund the RoI investigator(s), the partner agencies in NI fund the NI-based investigator(s), and the US partner agency, NIH, funds the US investigator(s).

2. Who are the partner agencies?

The partner agency in the US is the National Institutes of Health (NIH). The partner agencies in RoI are Science Foundation Ireland (SFI) and the Health Research Board (HRB). In Northern Ireland, the Health & Social Care R&D Division (HSC R&D) supports health-related projects, while the Department for the Economy (DfE), and Invest Northern Ireland (InvestNI) support projects related to Sensors & Sensor Networks, Nanoscale Science & Engineering, Telecommunications, and Energy & Sustainability.

3. Do US-Ireland R&D Partnership proposals have a competitive advantage with the NIH calls?

US-Ireland R&D Partnership proposals compete head-to-head with 'non-US-Ireland partnership' proposals submitted to the same call. The competitive advantage comes from the additive nature of the collaboration as well as the leveraged non-exchequer funds. It is important for applicants to spell this out in the introduction to the proposal to ensure that NIH reviewers fully understand the intricacies of the process.

4. Is the US-Ireland R&D Partnership call still open?

Yes, the call is open and is a rolling call, with deadlines throughout the year.

For applications to the NIH, there is a mandatory "intention to submit" stage where a notification MUST be submitted to SFI at least 10 weeks in advance of the NIH deadline.

Then, near-final applications MUST be submitted to SFI 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 NIH full proposal deadline.



Please note that the above timelines are the latest dates for submission of forms/proposals

5. When is the next NIH call deadline?

HRB/SFI has no control over the deadlines set by NIH. You are strongly advised to consult with your US partner for information on NIH call deadlines. The US partner makes the submission on behalf of the Northern Ireland & Republic of Ireland applicants and should therefore be familiar with NIH programmes and submission systems. Near-final drafts MUST be submitted to SFI 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 NIH full proposal deadline. For applications to the NIH, there is an additional intention to submit stage where a notification MUST be submitted at least 10 weeks in advance of the NIH deadline.

The following are the **standard** NIH deadlines for *new applications, and re-submissions* to the R01 programme. Please check with SFI what the corresponding deadlines are for the mandatory Intention to Submit, and near-final draft proposals. (SFI/HRB deadlines may shift slightly to accommodate, e.g. Christmas break periods).

Standard NIH R01 Deadline	Standard NIH R01 Deadlines
(New submissions)	(resubmissions)
February 5th	March 5th
June 5 th	July 5th
October 5 th	November 5th

6. Our US collaborator is able to submit to NIH outside of the standard R01 deadlines – when do I need to submit documentation?

HRB and SFI recognise that some US PIs who participate in the NIH Peer Review process are permitted to submit applications outside of standard deadlines. A non-standard deadline is acceptable to HRB and SFI, provided that (i) the non-standard deadline is indicated on the Intent to Submit Form at least 10 weeks prior to the deadline, (ii) you provide written confirmation (email is acceptable) from the PI confirming this non-standard deadline, (iii) the near-final draft is submitted at least 6 weeks prior to the deadline, as per our normal review process.

7. Why do I have to submit a draft of the proposal to HRB/SFI in advance of the NIH deadline?

A draft of the "tri-partite" proposal for submission to the NIH must be submitted to HRB at least 6 weeks in advance of the NIH deadline. During this six week period, the following process takes place: both HRB and SFI review the proposal jointly, request any additional clarifications/amendments, propose a recommendation to both agencies' Executive committees at one of their scheduled meetings, and secure a decision in order to prepare a Funding Commitment Letter/Letter of Regret.

HRB and SFI review the proposal to ensure that there is significant participation by all partners, to assess the budget requested, and to confirm that 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, and to assess the overall quality of the proposal. While the NIH peer review process will judge the scientific merit, if the supporting agencies had concerns on the overall quality of the proposal including e.g. completeness, clarity, grantsmanship, this would be raised with the investigator as part of the review process.

If HRB/SFI agree to support the proposal, a Funding Commitment Letter is provided to the applicant for inclusion in the full proposal to be submitted to NIH. This letter is also sent to the responsible person(s) at NIH to indicate our commitment to this proposal should it be deemed fundable by the NIH peer-review process. Please ensure that all relevant appendices are included with the draft proposal. A parallel process operates in Northern Ireland.

8. Where can I find information on eligible calls within the NIH? Which calls in NIH are open to the US-Ireland programme?

See link here for details of individual NIH Institutes which will have individual Funding Opportunity Announcements- NIH - Information on Institutes . Opportunities which solicit R01-type project applications are typically eligible.

You are encouraged to discuss your proposed research program (US, NI and RoI team) with the relevant program officer at the specific NIH institute before submission to ensure your proposed topic is of interest to, and aligns with the mission of that NIH Institute or centre. You can find assigned program officials by topic areas here: https://projectreporter.nih.gov/reporter_matchmaker.cfm

Please consult SFI if you are unsure whether a particular opportunity is eligible under the programme.

9. I'm an applicant based in Ireland, how can I find out about potential partners or research areas in the NIH?

RePORT - <u>www.report.nih.gov</u> - provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research.

RePORTER - <u>projectreporter.nih.gov</u>- a research a repository of NIH-funded research projects and provides access to publications and patents resulting from that funding.

10. I'm an applicant based in the States – how do I go about finding research partners in the Republic of Ireland & Northern Ireland?

Please contact the HRB and or/check the SFI research database on the SFI website.

11. I'm an applicant based in the States – do I need to submit any additional information in the NIH application?

The US partners need to be aware of the US Ireland Programme and how it operates but do not need to fulfil any additional steps outside of the normal application to NIH. However, the US partner should be advised that although they do not need to include the NI/RoI budget in their application, they need to provide the necessary collaboration and consortium agreements, as per their University's guidance.

12. Can anyone apply to this programme?

No, there are a number of eligibility criteria which you must meet, please consult the call guidance document Section 5.

13. What are the eligibility criteria for a co-applicant?

The eligibility criteria for co-applicants are the same as for the lead applicant – see question above. Please note only one US-Ireland application per applicant may be under review by HRB/SFI/NIH at any one time.

14. I'm an applicant from Northern Ireland, where can I find further information on the US-Ireland programme?

Please see links - <u>DfE - Further Information on US-Ireland programme</u>, <u>HSC R&D - Further information on US-Ireland Programme</u>

Intention to Submit Form

1. Who needs to complete the Intention to Submit form?

If you are applying to the NIH, you are required to send a mandatory "Intention to Submit" form to <u>USIreland@sfi.ie</u> at least 10 weeks in advance of the NIH deadline. Please see further information at <u>HRB</u> and on the SFI website.

2. Do all lead applicants and co-applicants have to complete the Intention to Submit form if applying to the NIH?

Yes, all lead and co-applicants in both Republic of Ireland (ROI) & Northern Ireland (NI) have to complete a single 'Intention to submit' form which must be submitted by the Research Office to the relevant funding agency. For example, if there is more than one RoI applicant proposing to participate in a US-Ireland proposal to the NIH, the Intention to Submit form to SFI must include relevant details for all such applicants. Submission of the Intention to Submit Form is mandatory for all applications to the National Institutes of Health (NIH).

3. I'm applying to the NIH under the sensors theme linked to health – do I need to submit an Intention to Submit form?

Yes – for any application to the NIH, a *mandatory intent to submit form is required at least 10 weeks prior to the NIH deadline*. Draft proposals to the NIH will only be accepted from applicants who have submitted an intention to submit form no later than 10 weeks in advance of the full proposal deadline at NIH.

4. What needs to be included in the scientific abstract in the Intention to submit form?

Please refer to the guidance document for further information.

FULL PROPOSAL

1. What research areas are covered under the US-Ireland programme?

The scheme is now open to **funding projects across the entirety of the NIH remit**. This means that for this scheme SFI will now consider research outside their <u>remit</u>, and HRB will open up beyond patient-oriented, population health and health services research remits.

2. What is the maximum funding request to HRB/SFI?

The budget for full applications from applicants in the Republic of Ireland has been increased to €700K direct costs. SFI/HRB also make an indirect or overhead contribution to the host Research Body, which is reflected as a percentage of the direct costs (30% excluding equipment). Overheads are payable as a contribution to the research body for the indirect costs of hosting SFI/HRB-funded research programmes and are intended to enable the research body to develop internationally competitive research infrastructure and support services.

3. Does HRB/SFI fund the salary of lead applicant or co-applicant?

HRB/SFI does not fund the salary of grant applicant/co-applicant. Please see Appendix 4 of the call Guidance for further details.

4. Where can I find more information about eligible costs for budget requests?

Please refer to Appendix 4 of the guidance document for further information.

5. Do both SFI & HRB have to agree approval before a proposal can be submitted to NIH?

Yes, both agencies have to review and agree to support the tri-partite proposal.

6. Are overheads included in the budget?

Only direct costs of up to a maximum of €700k should be detailed in the requested budget. The **overhead should not be included within the RoI budget request**; for successful projects, overheads will be applied at time of contract. HRB and SFI will contribute to the indirect costs of the research through an overhead payment of 30% of direct costs excluding equipment.

7. Are certain costs ineligible?

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

Costs falling within the <u>overhead contribution</u> 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 within the budget.

8. How do I submit to HRB/SFI?

Please convert all requested documents (see Section 7 guidance call document) to a single pdf (only the cover sheet with signatures should be scanned) and submit by email to USIreland@sfi.ie

9. What happens if I don't submit all documents as required by SFI by the 6 week deadline?

Incomplete documents will be returned without review. Applications received after the 6 week deadline prior to NIH submission will be returned without review.

10. I'm a researcher who has an Enterprise Ireland Commercialisation award (CFTD) for €300,000 - am I eligible to apply to the US-Ireland programme?

Unfortunately, the Enterprise Ireland Commercialisation Fund Technology Development (CFTD) awards do not satisfy the eligibility criteria for an internationally peer reviewed research award as these awards do not solely engage international peer reviewers.

11. Can the partner in Republic Of Ireland or Northern Ireland be an SME/ industry?

No the RoI and NI partners have to be based at an eligible Research Institution (refer to call guidance document for a list of eligible Research Institutions).

12. If my draft proposal is approved by HRB/SFI – what are the next steps?

- If approved by HRB/SFI for submission to the NIH, an approval notification email will be sent by SFI to
 the applicant which includes a Funding Commitment Letter confirming HRB and SFI's support of the
 research, for inclusion in the full proposal submission to NIH
- the Funding Commitment Letter will also be sent by SFI to the NIH
- The RoI applicant will need to submit a revised budget and signed cover sheet to SFI, if modifications
 have been made to the budget
- SFI requires a copy of the full proposal submission to NIH with official email confirmation including NIH proposal code.

13. What is the Funding Commitment Letter or FCL?

This is a letter of commitment from either the ROI or NI funding agencies confirming their support of the proposed research, and is to be included in the joint application to the NIH. The letter indicates the amount of funding committed by each jurisdiction to their applicant should the application be successful at the NIH review.

14. The title of the research proposal has changed - do I need to inform SFI or Northern Ireland funding agencies?

Please inform SFI at <u>UsIreland@sfi.ie</u> as soon as possible of *any* title change as the title listed in the Funding Commitment Letter (see above) needs to be accurate.

15. I received the scores from the NIH and it appears the application may not progress to the funding stage. My partners would now like to resubmit to the next NIH call. Do I need to resubmit to SFI?

Yes, please advise the SFI as soon as possible of your plan to resubmit. All resubmissions need to be reviewed by HRB/SFI to ensure there are no substantial changes to the research programme. Applicants must submit the updated near-final draft, updated budget, reviewers comments, the response to those comments, and a document outlining the changes in the proposal since the previous submission. Once it has been reviewed and if approved, a new Funding Commitment Letter (FCL) with details of the new call **must be issued** by SFI to the RoI PI. This should be included in the joint application to the NIH. Please submit the re-submission to SFI at least **6 weeks** in advance of the NIH or internal US university deadlines.

16. The US partners have decided to submit to a different call or Funding Opportunity announcement at the NIH. This is different to the original call/programme details sent to SFI.

This is a delayed submission and it will need to be reviewed by HRB/SFI to ensure that there are no substantial changes. Once it has been reviewed and if approved, a new Funding Commitment Letter with details of the new Call will be issued by SFI to the RoI PI. This FCL should be included in the joint application to the NIH or NSF. Please submit this application to SFI **6 weeks** in advance of the NIH or internal US university deadlines.

17. When do I need to send the resubmission/delayed application to SFI?

All resubmissions and delayed applications are required to be submitted to SFI *at least* **6 weeks** prior to any US partner institution/NIH submission deadline. This is the responsibility of the RoI partner and no early notifications of the outcome of the HRB/SFI review are possible.

18. How do I find out about upcoming workshops or webinars promoting the US-Ireland programme?

Please refer to the HRB and SFI websites.

NIH programme specific questions

1. Why would the NIH fund researchers outside of the US? Does one have to establish that the concepts are truly unique in that they cannot be carried out by investigators in the US? (This question refers to applications submitted by overseas applicants directly to the NIH and not submitted under the US-Ireland programme)

Proposed research from foreign organisations should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the U.S. or that augment existing U.S. resources.

2. What are the typical success rates for NIH programmes?

It depends on the Institute and program, up to date statistics can be found at https://report.nih.gov/

3. Is it a pre-requisite or merely a recommendation that the RoI and NI have previously collaborated on a project?

This isn't a prerequisite, but it is likely to strengthen the proposal.

4. Are further details required on the proposed collaborative aspects of the proposal?

Research teams with investigators from different institutions are expected to detail their proposed collaborations as part of the grant application. Therefore applicants should include letters of commitment or intent that clearly spell out the roles of the collaborators. These letters, together with the Funding Commitment Letter issued by SFI/HRB/HSC, should provide assurance to the reviewers that this work can be delivered, and that funding commitments are in place.

A formal agreement of the terms of the collaboration may be needed if your award is successful, but this is not usually required at the applications stage.

For information on consortium agreement please see:

https://grants.nih.gov/grants/policy/nihgps 2011/nihgps ch15.htm

5. Will US-Ireland R&D partnership applications be reviewed separately to standard US applications for the same call?

There is no differentiation.

6. The PIs of the 3 collaborators (US/RoI/NI) are encouraged to be quite senior and have received significant prior funding - this is actually somewhat restrictive in terms of who can apply from RoI/NI due to the smaller size of the research communities here. Would applications with 2 senior collaborators and 1 junior collaborator from each region be considered?

Applications with 2 senior collaborators and 1 junior collaborator will be considered. It is important to explain the role of each of the partners involved, their expertise in the proposed research, and hence the added value to the proposed research programme.

7. Can you search on existing projects on a particular subject area which are linked to an active FOA?

It is possible to search by topic and RePORTER will show you currently funded NIH projects.

8. How can we find out more about the NIH review process?

An overview of the peer review process is here. Your US collaborator experience in relation to submission to the NIH is critical: the programmes and priorities, peer review process, and ideally with key personnel within the NIH institute. The submission of the Funding Commitment Letter is the formal mechanism for advising the relevant NIH Institute of the proposal, however it is strongly encouraged that the NIH personnel supporting and managing the peer review process (e.g. the Scientific Review Officer) are made aware of the US-Ireland programme by the (US) Applicant, and that any questions they have are addressed prior to submission (by your US collaborator). Your US collaborator should know the most appropriate people in the institute to contact in this regard.

9. What happens if my application is successful?

If you have a score in the fundable range then you should inform the funding agencies in Ireland as soon as possible.

The funders in Ireland will need to receive a copy of the NIH Notice of Award (NoA) before they can issue their own Letter of Offer.