











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: October 2025

Close-to-final draft Tri-Partite Proposal **DEADLINE** – at least **6 weeks** in advance of NIH 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 Aims

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 (US), Republic of Ireland (RoI) & Northern Ireland (NI).

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 that would not be achieved by the Principal Investigator (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 seven thematic areas:

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

This guidance document outlines the submission process for 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.

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 **US**, partner agency is the **National Institutes of Health** (NIH)¹. The NIH consists of multiple agencies which offer a number of calls for proposals.
- The **Republic of Ireland** (RoI), partner agencies are **Research Ireland** and the **Health Research Board** (HRB)³.

¹ National Institutes of Health (https://grants.nih.gov/)

² Research Ireland (<u>https://www.researchireland.ie/</u>)

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

- The Northern Ireland (NI), partner agency is the Health & Social Care R&D Division (HSC R&D)
 - *HSC R&D Division have in place an arrangement with the UK Research and Innovation (UKRI) Medical Research Council (MRC) to co-fund the NI element of a number of the successful health related US Ireland Grants.

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 collaborative efforts. The Steering Group is supported by a Secretariat, provided by <a href="Intertweeting-

2 Remit

The US-Ireland R&D Partnership Programme covers the remit of the National Institutes of Health and supports the NIH Research Project Grant Program (R01). NIH is made up of 27 institutes and centers, each with a specific research agenda, often focusing on particular diseases or body systems. Please ensure that the research topic of your proposal is within the remit of the NIH program. 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.

For further information on the remit of individual Institutes, please visit the following link: https://www.nih.gov/institutes-nih.

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 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 scientific and technical merit review criteria. The funding agencies on the island of Ireland have agreed to accept the decisions of NIH with regard to the suitability for funding of individual proposals.

In the RoI, Research Ireland administers this scheme on behalf of Research Ireland and the HRB. Applications to the scheme are submitted to Research Ireland and then shared with the HRB.

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

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⁴ HSC R&D (https://research.hscni.net/)

4 Eligibility

Each proposal must have a minimum of one named partner from each jurisdiction (NI, US, and RoI).

4.1 Eligibility of Research Institutions

The Research Institution⁵ 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 (RoI) or Northern Ireland (NI)

Applications must come from eligible Research Institutions. **Appendix B** - List of Eligible Research InstitutionsAppendix A - Funding Agencies Policies and Procedures 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 usireland@researchireland.ie prior to submission.

4.2 Eligibility criteria for Applicants

Eligibility Criteria for Rol Applicants

(i) Applicant contract status

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

- a) A member of the academic staff of an eligible Research Institution (permanent or with a contract that covers the period of the grant), or
- b) A contract researcher with a contract that covers the period of the grant, 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 they will be fully responsible for at least the duration of the US-Ireland R&D Partnership Programme grant.
- c) An individual who will be recognised by the Research Institution upon receipt of the US Ireland R&D Partnership Programme grant 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

⁵ The term 'Research Institution' refers to approved <u>HRB Host Institutions</u> and those eligible under the <u>Research Ireland</u> <u>Eligible Research Bodies</u> policies, as well as the eligible Northern Ireland institutions.

- a) The applicant is expected to have demonstrated research independence through securing at least one independent research grant as PI or co-PI. The grant must have been competitively awarded and internationally and independently peer reviewed. Eligible research grants are expected to have supported at least one full-time equivalent, excluding the applicant(s), and include research team costs (e.g., materials and consumables). This excludes smaller grants such as travel grants, equipment grants, post-graduate fellowships, postdoctoral fellowships, and grants of short duration (12 months or less). Laboratory fit-out / setup funding, grants from the applicant's institution, and grants that have not been subject to external international peer review are also excluded.
- b) The applicant and any co-applicant(s) must have held a PhD or equivalent qualification⁶ for at least <u>five years</u> by the proposal deadline. Applicants holding an equivalent qualification may be eligible but should nevertheless seek approval from Research Ireland/HRB in advance of submitting a proposal.
- c) US-Ireland partner agencies will not accept a second application whilst the first application is under review.
- d) If an applicant/co-applicant has been successful in securing a US-Ireland R&D Partnership grant, they will not be entitled to apply for a subsequent grant until at least the last 18 months of their active grant.

In addition to the eligibility criteria the RoI funding agencies will not fund:

- Applications from individuals applying for, holding, or employed under funding received from the tobacco industry⁷;
- Applications from individuals applying for, holding, or employed under funding received from the alcohol industry and related actors⁸;
- 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.

Eligibility Criteria for NI 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 grant), or
- b) A contract researcher with a contract that covers the period of the grant, who is recognised

⁶ http://www.sfi.ie/funding/sfi-policies-and-quidance/eliqibility-related-information/index.xml

⁷ Any company, entity, or organisation involved in the development, production, promotion, marketing, or sale of tobacco in any country of the world. The term also includes any companies that are a subsidiary or a holding company or affiliate of the above. This also includes e-cigarette companies and non-tobacco related companies which are fully or partially owned by the tobacco industry.

⁸ Including social aspects/public relations organisations (SAPROs) funded by alcohol companies or trade associations in which such companies are members.

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 grant.

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 and evaluation criteria as the lead applicant.

(ii) Applicant Track Record

a) Applicants and any co-applicant(s) must have held a PhD for at least five years by the proposal deadline⁹.

The applicant is expected to have demonstrated research independence ¹⁰ through securing at least one independent research grant as Chief investigator (CI), PI or co-PI. The grant must have been competitively awarded and internationally and independently peer reviewed from a major research funder¹¹. Eligible research grants are expected to have supported at least one full-time equivalent, excluding the applicant(s), and include research team costs (e.g., materials and consumables). This excludes smaller grants such as travel grants, equipment grants, post-graduate fellowships, postdoctoral fellowships, and grants of short duration (12 months or less). Laboratory fit-out / setup funding, grants from the applicant's institution, and grants 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 grant, they will not usually be entitled to apply for a second grant until the last 18 months of their active grant. (NI applicants may contact HSC R&D Division regarding this criterion)

⁹The 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 2019 or earlier are eligible to apply in 2024 for example.

¹⁰ 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.

¹¹ e.g. UK Research and Innovation, UK Health Department (including HSC R&D itself), NIH, prestigious national or international charity, e.g. Wellcome Trust, Cancer Research UK, Diabetes UK etc.

5 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.

5.1 Rol Funding

Research Ireland and HRB operate in partnership for this programme and each contribute 50% to funding the research costs of the RoI partners.

Rol applicants may apply for direct costs of up to €700,000 (exclusive of overheads) for a 3-5 year duration project.

The grant will provide support for research-related costs including salary for research staff, MSc/PhD stipend, student fees, running costs, PPI costs, FAIR data management costs, equipment, travel and dissemination costs, and overheads contributions. The overheads contribution will be added during contracting stage.

One single budget template 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). A budget template is available from the Research Ireland website¹².

Applicants should follow the budget guidelines provided in **Appendix C** - Budget guidance for Rol applicants when completing their budget.

5.2 NI Funding

NI applicants may apply to HSC R&D for costs of up to £500,000 for a 3-5-year duration project,

The grant will provide support for research-related costs including salary for research staff, MSc/PhD stipend, student fees, running costs, PPI costs, travel and dissemination costs. The budget should be calculated at 80% of the Full Economic Cost (FEC) and include indirect and estate costs.

One single budget template should be completed by the NI partner and each line item should be fully detailed and justified in the budget justification (max. 3 pages). A budget template is available from the HSC R&D website¹³.

Applicants should follow the budget guidelines for NI applicants provided in **Appendix D** - Budget guidance for NI applicants - Budget guidance for NI applicants when completing their budget.

¹² https://www.researchireland.ie/funding/us-ireland/

¹³ https://research.hscni.net/us-ireland-rd-partnership-programme

6 Application Process

6.1 Notification of Intent to Submit

In order to participate in a US-Ireland R&D Partnership proposal, NI and RoI applicants 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 on the Research Ireland and HSC R&D websites 12,13.

- Name and Research Institution of the Rol, NI and US applicants
- Information regarding the eligibility of the RoI and NI applicants
- US Target Institute/Centre, Target R01 programme FOA/Notice Number, submission deadline
- Proposed topic, title of proposal, abstract
- Information regarding the expertise and expected budget request for each jurisdiction

For RoI applicants, please submit to <u>usireland@researchireland.ie</u>.

For NI applicants, please submit to <u>USIreland@hscni.net</u>.

Once received an eligibility check is carried out by Research Ireland and receipt shared between HRB and NI agencies.

The information in this form will be used for planning purposes by the agencies.

6.2 Submission of draft tri-partite proposal to funding agencies

In advance of submission of the final tri-partite proposal to the NIH, the funding agencies in Rol and NI 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 be submitted to the Rol and NI funding agencies at least 6 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 proposal:

- 1. Coversheet
- 2. Research Programme Overview
- 3. Potential Safety Risks and Ethical Concerns

- 4. Management & Communication Plan
- 5. Budget and budget justifications
- 6. Applicant CVs
- 7. Appendices
 - a) Added Value
 - b) Gannt Chart
 - c) Fair Data Management and Stewardship
 - d) Research Infrastructure Agreement Form (where applicable)
 - e) Letters of Support from Clinical Trial Sponsors (where applicable)
 - f) A foreign justification attachment (see section 7 below)

1. Coversheet

For RoI applicants, a standard Research Ireland/HRB coversheet signed by the applicant and approved by the appropriate signatory from their institution. A copy of the coversheet is available on the Research Ireland website¹⁴.

For NI applicants, a standard HSC R&D coversheet signed by the applicant and approved by the appropriate signatory from their institution. A copy of the coversheet is available on the HSC R&D website¹⁵.

2. Research Programme Overview

A detailed overview of the research programme, including a breakdown of the workpackages and tasks to be undertaken by partners in each jurisdiction. It should be clear who is responsible for each work package and objectives/deliverables, and it should be mapped against estimated completion timelines in a Gantt chart. We recommend including an image/diagram to show the workflow and links between work packages and governance of each jurisdiction.

3. Potential Safety Risks and Ethical Concerns

A section stating any potential risk and/or harm to patients or human subjects/participants in the research, if relevant.

For Rol applicants

Rol investigators and research institutions must ensure that, before the research commences and during the full grant 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. Research Ireland Policies and Positions and Guidance on Ethical and Scientific Issues can be found here.

¹⁴ <u>https://www.researchireland.ie/funding/us-ireland/</u>

¹⁵ https://research.hscni.net/us-ireland-rd-partnership-programme

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 Research Ireland 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 a grant, submission of ethical and regulatory approvals may be permitted following the grant start date but prior to commencement of the research involving animal and/or human subjects.

For NI applicants

For all grants 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.

4. Management & Communication Plan

A 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 efficient management and a successful outcome of the proposed partnership project.

5. Budget and budget justifications

Copies of the requested budget in each jurisdiction:

- For RoI applicants, details of the budget requested (using budget template provided on the Research Ireland website).
- For NI applicants, details of the budget requested (using HSC R&D budget template provided on the HSC R&D website).
- US applicants should use the standard NIH budget template.
- Budget justification for the funding requested by RoI and NI partners (max. 3 pages for each jurisdiction).

6. Applicant CVs

CVs of each applicant in each jurisdiction in NIH format. We recommend that this section highlights the most relevant experience of each applicant for their particular role on the application.

8. Appendices

Added Value

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.

Gannt Chart

If a Gantt chart or equivalent has not been included in the draft application, it should be included in the appendix.

Fair Data Management and Stewardship

Please provide a short data management plan (max. 2 pages) for the (RoI/NI) component(s) of the research project, ensuring that you address the aspects listed below. The purpose of this plan is to document the procedures that will be used to ensure good data governance and stewardship for research carried out in the (RoI/NI), but it may also make reference to data related to research carried out in the US, where appropriate.

A data management plan is a living document that should naturally be updated as data management tools evolve and procedures or project plans change during the term of grant. In the event of a grant being made, the tripartite research team should work collaboratively to ensure that appropriate data management practices are maintained in each jurisdiction and that up-to-date plans are maintained, available on request to the relevant funder(s).

Recommended areas for discussion in the data management plan:

- 1. Describe the data that will be associated with the project, in particular:
 - The data types that will be collected, created or re-used.
 - The formats that will be used and why they are appropriate for use.
 - The size/scale/volume of each data type.
- 2. Describe how data quality and metadata will be managed. Provide details on:
 - Standards, methodologies and quality control measures applied to the data and why they are appropriate or have been selected.
 - Metadata that will be created and the standards that will be applied to it to make it usable by others.
- 3. Explain the approach for data preservation and sharing, particularly:
 - How the data will be stored and backed up during the research process.
 - Which data will be preserved, how and where it will be stored in the longer-term, and for how long.
 - How data sharing and access will be facilitated and how the data will be made discoverable.
 - Any restrictions that will be placed on sharing, the rationale for these and when they would be lifted.
- 4. Summarise the access, security, legal and ethical requirements. Provide details on:
 - How data security and protection of sensitive data will be managed.
 - How legal issues such as IP rights and ownership will be managed.
 - Any ethical issues which must be taken into account.

Explain who will be responsible for data management and stewardship, and what resources will be needed or dedicated to make the data findable, accessible, interoperable and re-usable (FAIR) during the whole lifecycle of the data.

Research Infrastructure Agreement Form (where applicable)

Rol 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, Research Ireland-funded infrastructure) for the project. The following information must be provided in the **form provided on the Research Ireland website**¹⁶.

- 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.

Letters of Support from Clinical Trial Sponsors (where applicable)

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, HRB/Research Ireland 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.

A Foreign Justification Attachment

All applications must include a 'Foreign Justification' attachment. This should describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting. More information can be found at NOT-OD-25-098: Reminder: Application Requirements for Projects Involving Activities Outside of the United States or Partnerships with International Collaborators.

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

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¹⁶ https://www.researchireland.ie/funding/us-ireland/

7 Tri-partite draft proposal – review process and criteria

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

Eligibility including track record

Budget

- Value for money
- Budget requested adheres to guidelines

Added value

- Evidence of significant participation by all three partners
- 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

Overall quality

• The scientific merit of the proposal is not being accessed, but rather the completeness of the application, grantsmanship etc.

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

8 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.

Research Ireland/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 Research Ireland/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 submission code must be

sent to the relevant funding agencies by the applicants within two weeks of the NIH submission deadline.

NIH Research Security and Other Support Disclosure Policies

The NIH, along with other US federal funders, has introduced a requirement for all key/senior personnel on proposals to have undertaken training on research security and other support disclosure requirements (see notices NOT-OD-25-133 and NOT-OD-25-154). As a result, RoI and NI lead applicants and co-applicants may be required to demonstrate that they have completed the requisite training or that they have already undertaken equivalent training that conforms with the requirements of NOT-OD-25-133 and NOT-OD-25-154. RoI and NI applicants are **strongly encouraged to engage early with the US lead applicant and their host institution** to ascertain what their obligations are in order for their proposal to be submitted.

For additional guidance on full proposal submission please see the FAQ section on the programme websites for each agency^{17,18}.

9 Post Award Management

RoI based applicants receiving funding from Research Ireland and HRB will be subject to reporting requirements of Research Ireland. 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. Requirements for the post-award management of grants will be set out within the Grant General Terms and Conditions.

NI 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 grants will be set out within the Terms and Conditions of the Award.

For further information, RoI applicants should contact <u>usireland@researchireland.ie</u> and NI applicants should contact <u>USIreland@hscni.net</u>.

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¹⁷ https://www.researchireland.ie/funding/us-ireland/

https://research.hscni.net/us-ireland-rd-partnership-programme

Appendix A - Funding Agencies Policies and Procedures

FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support <u>open research</u>¹⁹ and open publishing directly through the <u>HRB Open Research platform</u>²⁰. The HRB is driving the making of research data **FAIR** (**F**indable, **A**ccessible, Interoperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability. Research Ireland's position on open research and data management can be found on their website²¹.

<u>FAIR data principles</u>²² provide a guideline for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals. For researchers, the move to FAIR and open data, where applicable, means researchers should consider data management issues and find suitable data repositories at the research planning stage. Applicants will have to provide information about their plans for data management and data sharing at application stage.

GDPR/privacy statements

Research Ireland Statement

The General Data Protection Regulation²³ is a legal framework that sets out guidelines for the collection and processing of personal information of individuals within the European Union²⁴. Applicants are advised that they must be compliant with this regulation if they collect or process personal data.

Research Ireland 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 Research Ireland. Further details regarding Research Ireland's collection, use and disclosure of personal data, and the rights of individuals with respect to any personal data held by Research Ireland, are available in the Research Ireland Privacy Statement²⁵.

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 Research Ireland, 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, Research Ireland may contact the Research Body, the Principal Investigator, or any member of the Research Team with regard to funding

¹⁹ http://www.hrb.ie/funding/policies-and-principles/open-research/

²⁰ https://hrbopenresearch.org/

²¹ https://www.researchireland.ie/about/policies/open-research/

²² https://www.nature.com/articles/sdata201618

²³ https://www.dataprotection.ie/

²⁴ https://gdpr-info.eu/

²⁵ <u>https://www.researchireland.ie/privacy-policy/</u>

opportunities, activities or events organised by Research Ireland 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). Research Ireland 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.

HRB statement

By participating in the US Ireland Partnership Programme, you will be asked to confirm you 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, Research Ireland, Health and Social Care NI support your application (i.e. the submission of the Funding Commitment Letters) and that HRB uses the information you provide (regarding all applicant team members) to consider your application and contact you about your application. We will publish some basic information on successful grants including PI, Host Institution, amount granted and lay summary on our website and may highlight individual grants 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 grants to help evaluate our career support and capacity building initiatives.

HSC R&D Division statement

Please see the HSC R&D Division Privacy notice: https://research.hscni.net/privacy-policy

The Health Research Regulations

Following the implementation of GDPR, a regulation for health research known as the Health Research Regulations 2018 (S.I. 314) has been implemented, with further amendments made in 2019 (S.I. 188) and 2021 (S.I. 18). These regulations outline the mandatory suitable and specific measures for the processing of personal data for the purposes of health research. They further set out that explicit consent is a mandatory safeguard that must be obtained from individuals when using their personal data for health research. Where it is not feasible to obtain explicit consent, an application for a consent declaration can be made to the Health Research Consent Declaration Committee.

Appeals

The Co-funding agencies reserve the right to reject any application that does not meet the eligibility criteria.

Rol

Research Irelands policy on appealing decisions is available at https://www.sfi.ie/funding/sfi-policies-and-guidance/review/.

The HRB's Policy on Appeals on eligibility decisions is available at https://www.hrb.ie/wpcontent/uploads/2024/09/HRB-Policy-on-Appeals-2.pdf.

NI

HSC R&D Division policy on appeals is available at https://research.hscni.net/hsc-rd-division-policy-appeals

Appendix B - 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 <u>both</u> recognised HRB Host Institutions <u>and</u> Research Ireland Eligible Research Bodies.

- Atlantic Technological University
- Dublin City University
- Economic and Social Research Institute
- Mary Immaculate College
- Munster Technological University
- National Cancer Registry Ireland
- National University of Ireland, Maynooth (Maynooth University)
- RCSI University of Medicine and Health Sciences
- South-East Technological University
- Teagasc
- Technological University Dublin
- Technological University of the Shannon: Midlands Midwest
- The University of Dublin (Trinity College Dublin)
- University College Cork
- University College Dublin
- University of Galway
- University of Limerick

If your Research Institution is not listed, please contact <u>usireland@researchireland.ie</u> 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 Trusthttp://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 C - Budget guidance for RoI applicants

1. Staff	Must be listed for each salaried personnel and include costs for the following subheadings (a-e):
a) Salary	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.
	Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure.
	Applicants should include annual pay increments for staff and related costs (pension contribution and employer's PRSI contribution) in the budget.
	Note: This scheme does not provide funding for the salary or benefits of applicants, coapplicants or collaborators within research institutions who are already in receipt of salary or benefits (unless applicants are explicitly required to support their own salaries as part of their contracts).
b) Employer's PRSI	Employer's PRSI contribution is calculated at a % of gross salary. Please confirm the correct PRSI rate with your institutional finance office.
c) Employer Pension Contribution	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).
	If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. 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 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, Research Ireland/HRB will not be liable for costs.
d) Postgraduate Stipend	A stipend for academic based post graduate researchers in line with current government guidelines as a flat rate, which is currently €25,000 per annum for
	up to two years for MSc degrees
	four years for PhD degrees
	The stipend is tax exempt and in no circumstances can the stipend be used to support postgraduate fees.

e) Postgraduate Fees

Fees for postgraduate researchers registered for a higher degree. Research Ireland/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.

- up to two years for MSc degrees
- four years for PhD degrees

Where the rate of the final year is reduced in line with the Institutional policy (e.g., some institutions might offer 50% reductions in fees in year four) the Research Ireland/HRB reserves the right to recover the unspent fees.

Please note:

• Postgraduate fees are paid at EU level only.

2. Equipment Costs

Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €50,000. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e., overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified. Depending on the nature of the project, high spec computers may be eligible and clear justification and rationale for the costs requested must be provided. 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, travel for participants, transcription costs, data access costs, maintenance costs of animals etc.

Access to necessary special facilities or services which are not available in the host academic or clinical institutions e.g. consultancy fees, methodological support, Clinical Research Facility support, access charges for Research Ireland-funded infrastructures, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form' (available on the Research Ireland website²⁶).

Costs associated with public and patient involvement in research. Some examples are:

- Compensating PPI contributors for their time (for example for time spent reviewing material/ participation in advisory groups). This can be as:
 - o a cost for their expertise, e.g. as hourly rate, under PPI costs or
 - as salaries under personnel which should be labelled PPI contributors under salaries.
- Travel expenses for PPI contributors.
- Costs associated with PPI contributors attending conferences, workshops, or training.
- PPI facilitator costs.
- Compensation of public or patient organisations for their time.
- Room hires for PPI events/meetings.
- Hospitality for PPI events/meetings.

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²⁶ <u>https://www.researchireland.ie/funding/us-ireland/</u>

- Companionship or childcare costs for PPI contributors while attending events, meetings, etc.
- Training in PPI in research.
- PPI contributors supported by salaries as research staff or co-applicants, where applicable in a scheme, should be listed and justified under the personnel heading.

All costs must be in line with the Host institutions' policies. Costs related to data-related and data management activities in line with best practice of data management and stewardship and the FAIR principles incurred during the lifetime of the project should be charged to running costs.

The following costs are <u>ineligible</u> 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 or membership fees

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.

4. Dissemination Costs

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 detailed in the dissemination and knowledge translation plan. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary).

Publications: Both Research Ireland and the HRB require that the outputs resulting from publicly funded research are made openly available. All peer-reviewed publications must be immediately available from the date of publication (no embargo permitted), under a Creative Commons attribution licence (CC-BY) or a CC-BY-ND licence by agreed exception. The funders will provide a contribution towards the costs associated with Article Processing Charges, when publishing in Open Access journals that are compliant with the funders policies²⁷. Typically, up to 1% of the overall value of a grant may be used for this purpose. Alternatively, applicants can consider HRB Open Research: rapid open peer reviewed and open access platform for all research outputs, with all publication charges covered centrally by the HRB at no expense to the grantee (http://www.hrbopenresearch.org/).

Conferences: We envisage that conference costs will be typically around €500 for national conference and €1,500 for international conference per person and year.

Overhead Contribution will be added by Research Ireland staff during contract negotiations for successful applications. It is not requested as part of the application budget. In accordance with the Research Ireland/HRB policy on Overhead Usage, the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (TDMC excludes student postgraduate fees, equipment, and capital building costs). The following items are included in the overhead contribution: recruitment costs, bench fees, office space, software, contribution to gases, bacteriological media preparation fees, waste fees, bioinformatics access. Therefore, these should not be included in the budget as direct costs.

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²⁷ https://www.researchireland.ie/about/policies/open-research/, https://www.hrb.ie/funding/responsible-research-assessment/open-access-policy/.

Appendix D - Budget guidance for NI applicants

Organisation	These are a share of the resources that cannot be directly attributed to an
costs (Overheads,	individual research project by nature of their activities. E.g. support services such
Indirect costs,	as libraries, HR, finance, maintenance, utility costs etc.
Estate costs)	Universities: HSC R&D Division provide research grants 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.
	HSC Trusts and Voluntary Sector Organisations: In most cases HSC R&D Division
	pay an agreed overhead on staff costs associated with the research.
	pay an agreed overnedd on stan costs associated with the research.
Salary costs	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 Grant 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.
	recruitment of starr to research organisations to work on runded projects.
Research	A contribution to research expenses incurred and claimed in a given financial year
Expenses/	will be paid. This can include: consumables required for the research project;
Consumables	travel expenses relevant to the project (excluding costs associated with travel
Consumables	
	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 Grant 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.
Travel Costs:	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.
PPI Costs:	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.
Exceptional	Directly incurred costs which are separated out because HSC R&D Division will fund
Items:	them at 100% of fEC rather than the standard 80%