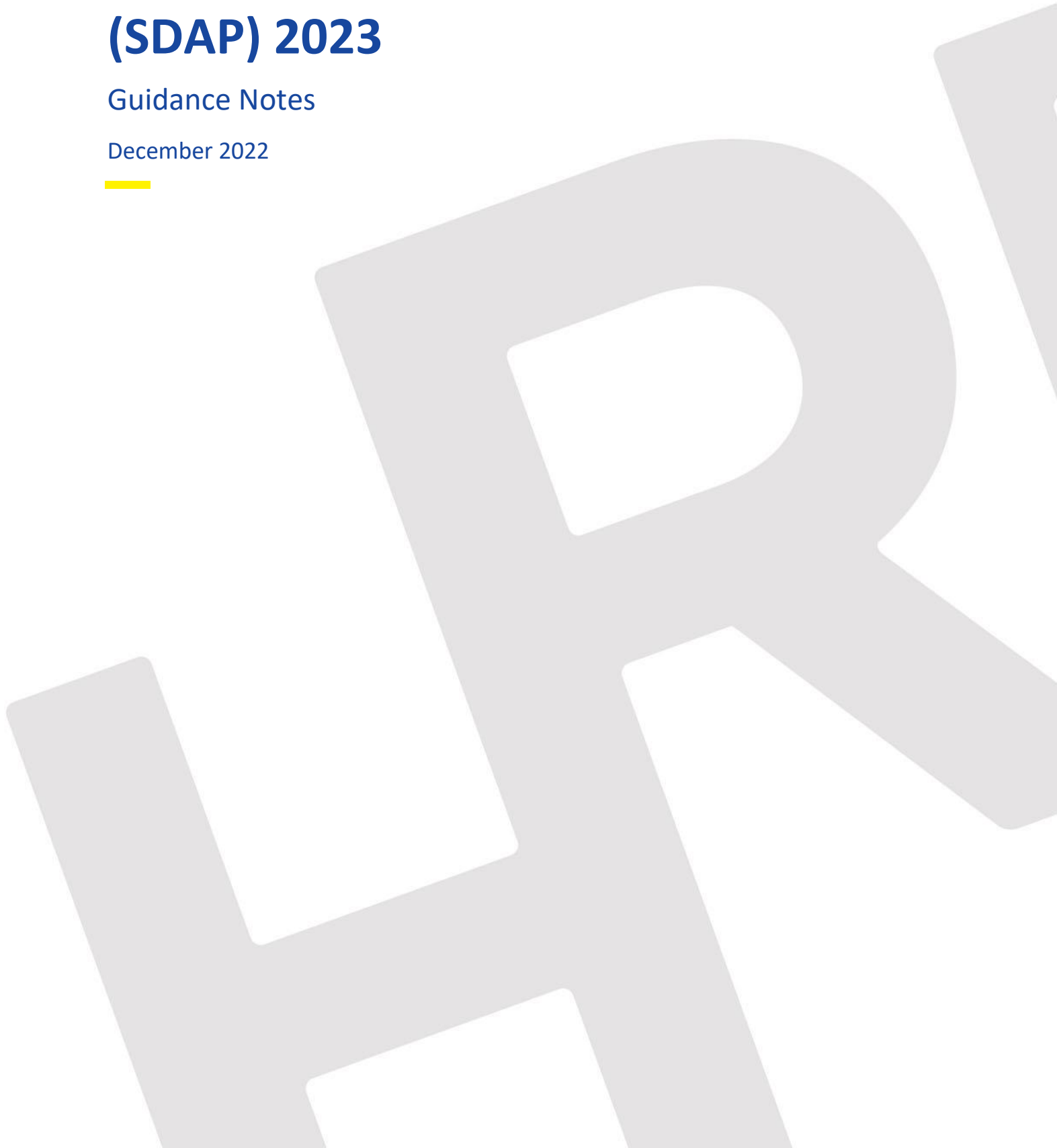


Secondary Data Analysis Projects (SDAP) 2023

Guidance Notes

December 2022



Guidance Notes

Key Dates	
Application Open	03 October 2022 @13:00
Application Closing Date – Cycle 1	15 December 2022 @13:00
Application Closing Date – Cycle 2	04 October 2023 @13:00

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (<https://grants.hrb.ie>), and this system will close automatically at the stated deadline and timeline listed above.

**Prior to final submission to the HRB, all applications must first be reviewed and approved within GEMS by the authorized approver at the Host Institution as listed in the application form. It is critical therefore that applicants leave sufficient time in the process for the Research Office (or equivalent) in their nominated Host Institution to review, seek clarifications and approve applications prior to the final submission date. This may involve being aware of and complying with any internal Host Institution deadlines for review and approval, distinct from the HRB deadline.*

Contents

- 1 Introduction..... 3
- 2 Aim and Objectives 5
- 3 Scope of the call..... 6
- 4 Funding Available, Duration and Start 6
- 5 Eligibility Criteria..... 8
- 6 Host Institution11
- 7 Application, Review Process and Review Criteria12
- 8 Timeframe15
- 9 Contacts15
- Appendix I: Detailed Guidance on the Application Form15
- Host Institution16
- Signatory Notification (within Host Institution)17
- 1 Lead Applicant’ details17
- 2 Co-Applicant Details.....18
- 3 Collaborator Details21
- 4 Project Details21
- 5 Project Description.....22
- 6 Details of the Research Team32
- 7 Infrastructure & Support33
- 8 Project Budget33
- 9 Ethical Approval.....37
- Appendix II: HRB Funding Policies and Procedures39
- Appendix III: Resources/Useful Links.....43
- Appendix IV: Definitions48

1 Introduction

Better access to, and use of, health and social care data has the potential to transform the way that healthcare is delivered as well as how we manage our own health. The Health Research Board (HRB) Strategy (2021-2025)¹ sets out a lead role of the HRB to promote and enable the use of data to shape health policy, enhance healthcare delivery, and drive broader research and innovation initiatives. It aims to **“play a leading role with other stakeholders to promote and enable the infrastructure and environment for the optimal use of health and social care data and statistical data for research”**. Investing in research projects which employ secondary data analysis and record linkage is essential to support this.

It is important, however, that such research projects take place under the auspices of a clear and transparent data governance framework and that the privacy, confidentiality and data protection rights of data subjects is preserved and to the fore, in line with the Data Protection Act 2018² and the Health Research Regulations of the 2018 Data Protection Act³. This is critical if the high level of public trust in health research in Ireland is to be maintained.

The HRB manages health information systems for drugs and alcohol, mental health, and disabilities⁴. The Department of Health, via the HRB or others, and the Department of Children, Equality, Disability, Integration and Youth have invested in a wide range of world-leading data resources such as longitudinal studies⁵ and survey data⁶. In addition, there is a vast amount of routine health and social care administrative data resources that are collected by the health and social care system through national patient registries⁷, population health registries⁸ and health surveillance programmes⁹, as well as Census and other Central Statistics Office data. A wealth of data related to COVID-19 is also available through the CSO’s COVID-19 data hub¹⁰, and a mechanism for accessing HSE data for research purposes through a partnership between the HRB, the CSO and the Department of Health through the COVID-19 Research Data Hub¹¹. The catalogue of national health and social care data collections in Ireland collated by HIQA lists 124 entries¹². These information sources are vital to developing and ensuring evidence-based decision-making for practice and policy.

The benefits of secondary data analysis include:

- Large numbers of patients can be studied, in some cases with complete coverage of particular populations, producing more reliable results.

¹ <https://www.hrb.ie/strategy-2025/>

² <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/pdf>

³ <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf>

⁴ HRB Data Collections and Evidence <http://www.hrb.ie/data-collections-evidence/>

⁵ The Irish Longitudinal Study on Ageing (TILDA), Intellectual Disability Supplement to TILDA (IDS TILDA), Growing Up in Ireland (GUI), Lifeways Cross-Generational Studies

⁶ Health Behaviour of School Aged Children, Healthy Ireland Survey, Survey of Lifestyles and Attitudes to Nutrition (SLAN)

⁷ National Cancer Registry Ireland, Cystic Fibrosis Registry of Ireland, The Irish Epilepsy and Pregnancy Register and the Irish Motor Neuron Disease Register

⁸ National Cancer Screening Programmes such as BreastCheck, CervicalCheck

⁹ Data held by the Health protection Surveillance Centre (e.g. infectious diseases and Clostridium difficile Enhanced Surveillance)

¹⁰ [The COVID-19 Data Research Hub \(hrb.ie\)](https://www.hrb.ie/covid-19-data-research-hub/)

¹¹ <https://covid19ireland-geohive.hub.arcgis.com/>

¹² <https://www.hiqa.ie/areas-we-work/health-information/data-collections>

- Secondary data analysis identifies important causes of disease and epidemics, demonstrates the long-term effects of treatment, and helps improve the planning and provision of services.
- It saves time and money relative to primary data research.
- It is not always possible to collect primary data for some research questions.

Many data sets in Ireland are not used to the full extent possible to inform decision-making. The Secondary Data Analysis Projects (SDAP) scheme aims to optimise the use and re-use of data for the secondary purposes of research to generate evidence to inform policy and practice in health and social care.

Health research is conducted with the expectation that it advances knowledge and eventually translates into improved health systems and population health. However, research findings are often caught in the know-do gap: they are sometimes not acted upon in a timely way or are not applied at all.

The SDAP scheme requires applicants to follow the Integrated knowledge translation (iKT)¹³ model, coined by the Canadian Institutes of Health Research (CIHR), a research co-production model whereby researchers partner with **knowledge users** throughout the research process from the identification of the research issue and question/s through to translation of the research findings into policy and/or practice.

Engaging ‘knowledge users in the research process from idea formulation to dissemination and implementation has been proposed as the funding model most likely to ensure that research findings are relevant and responsive and can influence decision making in the health and social care system. Integrated Knowledge Translation (iKT)¹² (see Box 1) has advanced as a way to increase the relevance, applicability and impact of research. With iKT, knowledge users work with researchers throughout the research process, starting with identification of the research question.

Box 1 - integrated Knowledge Translation (iKT)

To describe researcher/knowledge user partnership funding models the Canadian Institutes of Health Research (CIHR) coined the term ‘integrated knowledge translation’ (iKT)¹³ and differentiated this from end-of-grant knowledge translation (KT). The ‘end-of-grant’ translation activities refer to those that are developed and implemented for making knowledge users aware of the research that was gained during a project. Such ‘diffusion’ and ‘dissemination’ activities are important in bridging the research to action gap and the HRB has responded to this through the establishment of its innovative *Knowledge Exchange and Dissemination Awards* (KEDS). In adopting the broader iKT approaches, however, a key defining factor is that researchers and knowledge users should engage as partners throughout the research cycle from identification of the research issue and question right through to translation of the research findings into policy and/or practice, thus ensuring that the research is relevant to knowledge users and more likely to be used by them.

The SDAP scheme will provide co-funded support for research projects that are co-created by a partnership of knowledge users and researchers. A **knowledge user** is defined as one in a position of

¹³ Guide to knowledge translation planning at CIHR: integrated and end of grant approaches [<http://www.cihr-irsc.gc.ca/e/45321.html>]

authority to influence and/or make decisions about health policy or the delivery of services and can act to ensure that the findings of the research will be translated to influence decision-making and change within their (or other) organisations. This is typically a health-system manager, policy maker, health professional or clinician who is in a position to make significant changes to policy or practice. Knowledge User organisations may be Government departments, agencies, hospitals, local government, voluntary organisations, research charities, patient/consumer groups or other organisations involved in making decisions regarding the management, structuring and/or delivery of practice or policy in the Irish health and social care system.

The iKT model ensures that the research is relevant to knowledge users and therefore more likely to be used by them as this funding model has been identified as the most likely to ensure that research findings are relevant and responsive and can influence decision-making in the health and social care system^{14,15}. The HRB is now launching this call designed at encouraging and incentivising researchers to conduct secondary data analysis which supports policy and practice decision-making for health and social care.

2 Aim and Objectives

The overall aim of the scheme is to optimise the use of existing health and social care data sources to deliver high-quality, high-impact evidence for policy and/or practice.

There are three key objectives:

- i. To answer policy and/or practice-relevant questions using secondary data.
- ii. To develop and strengthen partnerships between researchers, data controllers and knowledge users in the area of secondary data analysis.
- iii. To enhance capacity for further research of this nature in Ireland through upskilling, training and education of team members where possible.

A key element in the design of this scheme is to ensure that the research funded is relevant, high quality and in the public interest and that the work is progressed in accordance with the principles of good governance and transparency, and with robust and appropriate safeguards in place to ensure that the privacy, confidentiality and data protection rights of data subjects are to the fore.

¹⁴ See Sibbald et al. (2014). Research funder required research partnerships: a qualitative inquiry. *Implementation Science*, 9:176.

¹⁵ Rycroft-Malone et al. (2015) Collective action for knowledge mobilisation: a realistic evaluation of the Collaborations for Leadership in Applied Health Research and Care (CLAHRC), *Health Services and Delivery Research*, Vol 3; No 44. [<http://www.journalslibrary.nihr.ac.uk/hsdr/volume-3/issue-44>]

3 Scope of the call

The SDAP awards will support proposals where the findings from the research will have direct relevance to policy and/or practice in the Irish health and social care system. This should involve the close collaboration of researchers with relevant stakeholders including decision makers and data custodians/controllers. The proposed research should be explicitly linked to the documented evidence needs of the Knowledge User organisation.

Proposals must include at least one existing Irish or international dataset to be eligible for this call. Applications may be related to but must be distinct from, the specific aims of the original data collection.

Note: Documented evidence needs to relate to the research priorities or needs of the knowledge user. The proposed research should be explicitly linked to the documented evidence needs of the knowledge user organisation/s and this should be made clear in the application. It is the responsibility of the Lead Applicant to clearly define what these are.

The scheme will **not** fund:

- Projects involving additional primary data collection studies or bio-specimen analysis.
- Projects seeking to design and evaluate a trial or intervention. The HRB funds such projects through the Definitive Interventions and Feasibility Awards.
- Applications from individuals applying for, holding, or employed under a research grant from the tobacco industry.

We expect that evidence supporting the case for the project has been gathered systematically, i.e., as systematic reviews or other evidence synthesis formats. Simple literature overviews are not sufficient. Evidence synthesised systematically should include evidence of (1) a systematic identification of previous work, (2) critical appraisal, (3) synthesis of the evidence and (4) interpretation of findings.

Where an application is outside the scope of the scheme, the application will be deemed ineligible and will not be accepted for review.

4 Funding Available, Duration and Start

The SDAP 2023 will provide funding for projects up to a maximum of €250,000 (inclusive of overheads) per award. The HRB plans to commit in the region of up to €2 million to the SDAP 2023 Awards.

Quality permitting a minimum of 8 awards will be funded. Awards will have a typical duration of between 18-24 months.

The award will offer research related costs including salary for research staff, running costs, FAIR data management costs, equipment and dissemination costs, and overheads contributions.

Note: The SDAP 2023 award will not fund the salary and related costs of tenured academic staff within research institutions (including buy-out from teaching time etc.).

The budget requested and the award duration **must** reflect the scale and nature of the proposed research, and reviewers will thoroughly assess the level of funds and timeframe requested when reviewing the application.

Although not mandatory, co-funding from project partners may also be included either as contributions in-kind, or combinations of cash and in-kind contributions. A letter of commitment in respect of the co-funding is required.

We recognise that some data sets are not currently in an accessible format. Therefore, proposals are welcome for projects that include some aspect of development or improvement by the data provider/s to make datasets more accessible for research purposes in accordance with international best practice and ensures that the privacy, confidentiality and data protection rights of data subjects are preserved in line with the Data Protection Act 2018¹⁶ and the Health Research Regulations of the 2018 Data Protection Act¹⁷ (e.g., through the creation of a published data dictionary, use of encryption on de-identification techniques). In these cases, the duration of the award may be up to 36 months, with up to 12 months dedicated to the development of improved protocols and tools that make the datasets more accessible for research purposes and following best practice appropriate safeguards.

The earliest start date for Cycle 1 is 1 October 2023.

4.1 Dataset Requirements

- A dataset must meet the standards of the HIQA Information Management Standards for Health and Social Care Data Collections¹⁸.
- Data Controller(s) must agree to provide access to the dataset. Where a Co-Applicant is the Data Controller of the data set, the application must include a letter of support from the Data Controller or Joint Data Controller granting access to the data set. For Collaborators, this information will be captured in the Collaborator Agreement Form.
- Exceptions for the need for a letter of support granting access to the dataset are:
 - Where a dataset is publicly available, details must be included in the application. A separate letter of support from the data controller is not required.
 - For datasets held by the CSO where permission to access data is under review, a ‘letter of comfort’ indicating access has been applied for is sufficient at the application stage. Confirmation of access will be required at contracting for successful awards.
 - Where the process to allow access to data only commences once research funding has been secured, correspondence from the data controller that the data is available for access will be required at time of HRB application submission. Confirmation of access will be required at contracting for successful awards.

¹⁶ <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/pdf>

¹⁷ <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf>

¹⁸ <https://www.hiqa.ie/sites/default/files/2017-02/Information-management-standards-for-national-health-and-social-care-data-collections.pdf>

5 Eligibility Criteria

5.1 Applicant Team

Applications should be made on behalf of a team made up of **researchers, knowledge users and data controllers**.

- The Lead Applicant and Co-Applicant(s) **must include** a researcher and a knowledge user. This is an eligibility requirement of the scheme.
- Data controllers from data provider organisations should ideally be included as Co-Applicants or Collaborators.
- At a minimum, the data controller of the organisation providing access to the dataset/s must agree to provide access to the dataset.
- PPI Contributors should be included as part of the team where appropriate.

In some instances, a researcher or a knowledge user may also be the data controller/processor. The applicant team should designate a Lead Applicant from the research team.

The applicant team must demonstrate clearly that the appropriate and relevant partners are involved to achieve the objectives set out in the research proposal and in a manner that aligns well with the sections included in the application on relevance, knowledge translation plan and impact.

Applicants must demonstrate that the research team contains the necessary breadth and depth of expertise in all the methodological areas required to deliver the proposed study. Appropriate multi and inter disciplinary involvement in the research team is essential. As appropriate to the proposed study, experts in statistics¹⁹, PPI contributors, health service research, qualitative research methodologies, etc. should be included as Co-Applicants or as official Collaborators or requested as funded personnel. **Statistical expertise** should ideally be within the applicant team, rather than outsourced. Such expertise is required at the outset to engage with the data providers to assess the variables, quality and strengths and limitations of the available data for answering the research questions posed, to ensure the study is adequately powered and to support the development of the data analysis and management plan to be detailed in the application.

Roles and responsibilities of funded personnel must be differentiated and clear. Reviewers will thoroughly assess the level of experience matched with the supervisory and up-skilling arrangements proposed in scoring the application.

The HRB expects that applicants will collaborate, where appropriate, with partner organisations such as hospitals, health agencies, universities, local government, voluntary organisations and/or industry. The HRB encourages applicants to secure co-funding, where possible, from partner organisations. Applicants must also demonstrate the commitment of their partner organisations with evidence of existing partnerships and/or plans on how they will contribute to this award.

¹⁹ This round of SDAP now encourages education and upskilling of team members in areas that enhance capacity for future secondary data analysis; this would include in statistics

5.1.1 Lead Applicant

The **Lead Applicant** will serve as the primary point of contact for the HRB during the review process and on the award, if successful. The Lead Applicant will be responsible for the scientific and technical direction of the research programme. They **have primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of the HRB.**

For this scheme, the HRB welcomes applications from Lead Applicants with a background in fields other than health-related research. Applications utilizing the HRB's National Health Information Systems are encouraged; however, HRB staff cannot act as the Lead Applicant.

The Lead Applicant **must**:

- Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland (the "Host Institution") as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable, **OR**
- Be a contract researcher recognised by the Host institution as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible, **OR**
- Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of the award, for which they will be fully responsible. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission.

The Lead Applicant **must** show evidence of achievement as an independent researcher in his/her chosen research field by:

- a) Demonstrating a record of research output, with at least three publications of original research in peer-reviewed journals. Where appropriate, they should also provide evidence of other outputs. Where appropriate, they should also provide evidence of other outputs (e.g., published book chapters, reports to government, research data and datasets, research materials, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence on health policy and practice, outreach and/or knowledge exchange activities, media coverage or other relevant activities) and/or any other relevant outputs that have resulted in a significant impact in their field.
- b) Demonstrating a record of independence by showing that they have secured at least one peer-reviewed research grant for a research project/s, as either the Lead Applicant or a Co-Applicant. Funding received for travel to seminars/conferences and/or small personal bursaries will not be considered in this regard.
- c) Show evidence that they possess the capability and authority to manage and supervise the research team.

Only one application per Lead Applicant to this scheme will be considered.

Where an applicant fails to meet the eligibility criteria, the application will be deemed ineligible and will not be accepted for review. The HRB will contact the Lead Applicant in the event that this situation arises.

5.1.2 Co-Applicants

Co-Applicants will be asked to select whether they are a **Researcher, Knowledge User, Data Controller, Data Processor, or PPI contributor** co-applicant for the proposed research. Up to a maximum of **10 Co-applicants** can be listed. Note: It is not mandatory to have 10 Co-Applicants but this is to allow for flexibility should this be appropriate

See Appendix IV for the definitions of Researcher, Knowledge User, Data Controller, Data Processor and Appendix II: HRB Funding Policies and Procedures for further information on PPI.

A Co-Applicant has a well-defined, critical, and substantial role in the conduct and steering of the proposed research. Co-Applicants from outside of the Republic of Ireland are welcome where this is appropriately justified in terms of added value for the project. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards his/her own salary if they are in salaried positions. However, Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to the research for the duration of the award if they are contract/independent investigators. PPI contributors should be named as Co-applicants where justified by their level of involvement

Each Co-Applicant must confirm their participation and is invited to view the application form online. The terms of any co-application should be determined early, and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up co-application agreements.

Data provider organizations **should preferably be** included as co-applicants or collaborators²⁰. Please confirm the name of the data controller for the named datasets.

5.1.3 Collaborators

An official Collaborator is an individual or an organisation who will have an integral and discrete role in delivering the research activities and is eligible to request funding from the award when properly justified. A collaborator may provide training, provide access to specific equipment, specialist staff time, access to data or protocols or may act in an advisory capacity. Named collaborators may include investigators or organisations from outside the Republic of Ireland, but an individual or organisation should **only** be named as a Collaborator if they are providing specific contributions (either direct or indirect) to the activities. Collaborators can come from a range of backgrounds, for example, academia, the private sector, a healthcare organisation, the charity sector or a patient group (**up to a maximum of 10 Collaborators can be listed**).

Profile details must be provided for ALL official collaborators. In addition, each official collaborator must complete a Collaboration Agreement Form. A template Collaborator Agreement form will be made available on GEMS for download. Collaborators may be based outside the Republic of Ireland where appropriate and justified.

The applicant team will be asked to describe any relevant agreements that they have entered into to facilitate their partnership working. The HRB advise that consideration should be given to issues as

²⁰ This may not be possible in all cases; one example is using data from the UK Biobank

relative responsibilities, governance arrangements, ownership and copyright, access and sharing of data/materials etc. when working up Partnership proposals.

5.1.4 Funded Personnel

Applicants must demonstrate that the level, expertise, and experience of proposed research personnel matches the ambition and scale of the project and that they possess the necessary breadth and skills in all methodological areas required to deliver the proposed programme of work.

Alignment between personnel requested and the proposed project should be demonstrated. Roles and responsibilities of funded personnel must be differentiated and clear.

The SDAP scheme is not framed as a training initiative and the duration and nature of the SDAP project is not suitable for students in pursuit of a higher degree. However, **applicants are encouraged to provide education and training opportunities for the team in areas appropriate to secondary data analysis**, with particular attention to deepening skills in statistical analysis. Furthermore, in considering the broader skillsets needed to deliver SDAP projects such as working across diverse knowledge user and academic settings, applicants may wish to facilitate exchange or placement opportunities between partner organisations for funded personnel during the award. Both national and international placements could be considered for this purpose.

Reviewers will thoroughly assess the level of experience matched with the supervisory and up-skilling arrangements proposed in scoring the application.

6 Host Institution

A HRB Host Institution is a research-performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all of the HRB's award schemes. The **Host Institution for the award** is normally that of the **Lead Applicant Researcher** but it may be another organisation/institution designated by the research team, where it is clearly justified. To be eligible to apply for funding, an Institution must be an approved HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for research-performing organisations to be approved as HRB Host Institutions can be found on the HRB website²¹.

Host Institution Letters of Support must be provided for **(1) all Lead Applicants Researchers in a contract position and (2) Co-Applicants Researchers in a contract position who are seeking their own salary**. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information; [Host Institution - insert name] which is the host institution of [applicant - insert name] confirms that [applicant - insert name]: (i) holds an employment contract which extends until [insert date] or will be recognized by the host institution upon receipt of the HRB SDAP award as a contract researcher; (ii) has an independent office and research space/facilities for which they are fully responsible for at least the

²¹ [HRB Host Institutions](#)

duration of the award, and (iii) has the capability and authority to mentor and supervise the research team. Electronic signatures are acceptable for letters that are uploaded to the HRB GEMS system.

It is the responsibility of the Lead Applicant to ensure that applications are completed in full, and all necessary documentation is received by the HRB on, or before, the closing dates indicated.

This call is not open for Host Institutions from Northern Ireland.

7 Application, Review Process and Review Criteria

7.1 Grant E-Management System (GEMS)

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (<https://grants.hrb.ie/>). GEMS will close the **Cycle 1** Application automatically at **1pm on 15 December 2022**.

The application must have been reviewed and approved by the signatory approver at the research office (or equivalent) in the Host Institution before it is submitted to the HRB. Therefore, applicants should ensure that they give the signatory approver sufficient time before the scheme closing date to review the application and approve it on GEMS. Please note that many host institutions specify internal deadlines for this procedure. The HRB is committed to an open and competitive process underpinned by international peer review. To ensure the integrity of the assessment process, conflict of interest and confidentiality are applied rigorously in each stage of the process.

7.2 HRB Gender Policy

In line with international best practice, the **HRB Gender Policy**²² recognises the responsibility the HRB has to support everyone to realise their full potential in order to ensure equality of opportunity and to maximise the quantity and the quality of research. To ensure fairness and equality to all applicants, each funding application received will be assessed as outlined in the call guidance documentation for that particular funding round. Applicants to SDAP 2023 will be asked to carefully consider any potential gender and/or sex differences that may arise for the particular study, and how that will be accounted for during design, conduct, analysis and dissemination of the research (See Appendix III for resources on sex and/or gender in research).

To ensure gender balance in decision-making, the HRB aims to reach the international best practice target of 40% of the **under-represented gender** in all HRB panels where possible. Gender will also be considered when appointing the position of Panel Chair. Gender balance of the Lead Applicants of the research team will be among the ranking factors to prioritise proposals with the same scores in the Panel ranking list.

7.3 Review Process

Following an initial eligibility check, the proposals submitted to this scheme will undergo a two-phase review process.

Phase 1 – International Peer Review, Public Review and Applicant Response

²² <http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-gender-in-research-funding/>

For each eligible application the HRB aims to receive written feedback from at least three international peer reviewers and two public reviewers.

International peer reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Peer reviewers will focus on the scientific criteria only and will provide comments as well as a score. They have the option to provide comments on the knowledge translation criteria should they wish. The individual scores received from the international peer reviewers for each application will be averaged by the HRB and a short list compiled.

Public reviewers will only assess the quality of PPI in the proposal, they will provide comments and a rating but not a score. The public review comments and rating will be shared with applicants and the review panel.

Public Reviewers are asked to comment on the following:

- The Plain English Summary (Lay Summary)
- Relevance of the Proposed Research Question
- Public and Patient and Carer Involvement in development of and throughout the project
- Research Design
- Dissemination of the Proposed Work.

The HRB will share the public review feedback with the PPI Ignite Network team in the host institution where applicable.

Applicant Response

The applicant team will be provided with a time-limited opportunity to respond to peer and public review comments. Neither peer nor public review comments will include any reference to the reviewer's identity. Public review ratings will be shared.

Peer review and public review comments will be made available to the Lead Applicant on their GEMS personal page. The Lead Applicant will have 5 working days to submit their response through GEMS, and the response has a **maximum word count of 2500 words**, including references. This wordcount is broken down into **2000 words only for the peer review response** and **500 words only for the public review response**. The response will be provided to members of the Review Panel, in advance of the Panel meeting, along with the application, the peer and public review comments and rating.

This phase of the assessment process is extremely important, and the response will likely play a critical role in whether a proposal ultimately gets recommended for funding or not. It provides an opportunity to address any factual errors, conceptual misunderstandings or differences of opinion that can be perceived as weaknesses or concerns. It also provides the applicant team with an opportunity to take on board any constructive feedback that may help to improve the application, if funded, or future grant applications.

In order to make best use of this opportunity the response should be succinct yet clear and comprehensive. It should address all of the significant concerns and/or weaknesses described in the reviewer's feedback, rather than repeat positive remarks by the reviewers. If the applicant team disagrees with a reviewer's statement they should explain why and provide additional information. If the applicant team cannot address an issue, they should, at a minimum, acknowledge it. Responses

that could be construed as argumentative in tone should be avoided. Please note HRB reviewers volunteer their own time in reviewing grant applications.

Phase 2 – International Panel Review

Following the applicant response, a grant selection panel consisting of national and international members will be convened to discuss applications. In addition to scientific and methodological experts, panel members from knowledge user organisations will be invited to participate.

The panel will review the strengths and weaknesses of the application relating to the scientific and knowledge translation criteria detailed below. Successful applications will be expected to be rated highly on both assessment criteria before being recommended for funding. While PPI is not a stand-alone scoring criterion, Panel reviewers will also consider the public reviews and the applicant team's response to the public reviews, to inform their review.

Applications recommended for funding by the grant panel will be submitted to the Board of the HRB for approval. A summary of Panel Member's comments and the panel discussion comments will be issued to the Lead Applicant following the conclusion of the review process.

Review Criteria

Reviewers are asked to note the review criteria below and are asked to outline the strengths and weaknesses of the application.

Peer reviewers will provide a single score taking into consideration **the scientific criteria**. However, peer reviewers have the option to provide comments on the knowledge translation criterion should they wish.

Panel members will provide a single score taking into consideration **all** criteria.

The scientific criteria are weighted equally to the knowledge translation criterion.

Scientific Criteria

- Does the research address a policy or practice question/s relevant to the Irish health and social care system?
- Will the research design and methodology answer the research question/s?
- Does the research team have the expertise and experience to deliver on the proposed project?
- Do the proposed processes, protocols and safeguards reflect best practice data governance?
- Is it a genuine partnership between researchers, data controllers/processors, PPI contributors and knowledge users?
- Where possible, are there plans for relevant education and training in skills relevant to secondary data analysis?

Knowledge Translation Criteria

- Is there potential for impact policy and/or practice in Ireland and beyond within 1-2 years post project?
- Are there credible plans described to enable ongoing deliberation between researchers and knowledge users and to translate findings and learnings into policy and/or practice throughout the project (not just at the end)?
- Is there appropriate justification for the KT approach being proposed?

For applications applying for additional time to develop protocols, practices and tools:

- Will the project contribute to improving the future accessibility of a dataset for research purposes in accordance with best practice and transparent data governance processes?

Panel members will be advised to take PPI approaches into consideration under any of the assessment criteria if considered relevant beyond the specific reference under partnership.

8 Timeframe

KEY DATES	
Cycle 1	
Call open to applicants	03 October 2022 1pm
Closing date	15 December 2022 1pm
Peer Review period	January – March 2023
Applicant Response	Late March 2023
Panel meeting	May 2023
Award Start from	1 October 2023
Cycle 2	
Closing Date	04 October 2023
Peer Review Period	October – December 2023
Applicant Response	Early January 2024
Panel meeting	March 2024
Award Start from	June 2024

9 Contacts

For further information on the Secondary Data Analysis Projects awards contact:

Christina Rushe
Project Officer
E. crushe@hrb.ie

The HRB reserves the right to reject any application that does not meet the terms of this call.

Appendix I: Detailed Guidance on the Application Form

Secondary data Analysis Projects (SDAP) 2023 – Guidance Notes

Only registered users of the GEMS system can apply for grants. In order to submit an online application to the HRB, applicants are required to register at the following address: <https://grants.hrb.ie>. The **Lead Applicant** must create the application, but it can then be jointly completed with named co-applicants.

Lead Applicants can register on GEMS and they will receive an email to confirm their registration and log in details. The Lead Applicant can then add information on their contact and CV details in ‘Manage My Details’ section of GEMS. Lead Applicants previously registered on GEMS can login to GEMS and update any information regarding their contact and CV details in ‘Manage my details’. Once logged in to GEMS applicants are taken directly to the Home page which is the starting point to create a new Grant application.

The Lead Applicant will be asked to complete a check list of mandatory questions. In order to access the application form, the Lead Applicant must satisfy the conditions of this check list. The checklist for the SDAP 2023 is as follows:

Lead Applicant Eligibility	
I have read the Guidance Notes for the 2023 call and reviewed the main changes applied to the 2023.	<input checked="" type="checkbox"/>
I am clear about the role of the authorised signatory in the nominated Host Institution, and I am aware that I need to build sufficient time into the application process for the HI to access, review and approve my final application for submission to the HRB through the GEMS system.	<input checked="" type="checkbox"/>
I can confirm that each of the datasets proposed for this project are aligned with the scheme requirements, meeting the standards of the HIQA Information Management Standards for Health and Social Care Data Collections ¹⁷ , as per the SDAP 2023 Guidance Notes	<input checked="" type="checkbox"/>
I can confirm that the (Co-applicant team) fulfils the requirement of research and knowledge user	<input checked="" type="checkbox"/>
I can confirm that no primary data collection is required for this project	<input checked="" type="checkbox"/>
By submitting this application, I consent to (a) sharing of my data outside of the European Economic Area (EEA) for the purpose of international peer review, and (b) the use of my data for assessment of my application; monitoring of successful awards; and evaluation of HRB’s approach to funding and investment in research, in line with HRB policies and as detailed in the SDAP 2023 Call Guidance Notes.	<input checked="" type="checkbox"/>

The Lead Applicant will be then able to start the application. Further details for completing each of the main sections of the application form are provided below.

Host Institution

For the purposes of contracting, payment and management of the award, HRB funds can only be awarded to HRB approved Host Institutions. For this scheme, Host Institutions are limited to the Republic of Ireland. The Host Institution is normally that of the **Lead Applicant**, but it may be another organisation/institution designated by the research team, where it is clearly justified.

In GEMS you will be asked to identify a Host Institution (from [this list](#)) and type it in full (do not use acronyms such as UCD, TCD, NUIG). Once you have entered the first 3-4 characters of the Host Institution, you will be assisted with auto-select options. It is important that the Host Institution

name is entered accurately and in full as an incorrect entry may result in delays in attaining Host Institution approvals.

The Host Institution will review and administer the HRB grant funding and is responsible for compliance with all general and specific terms and conditions of the award. You should take care when entering your Host Institution as once entered, a button will appear on the next page (Signatory Notification) which will allow you to notify your Host Institution of your intention to apply.

Note: Only organisations listed on the policy page of our website which have satisfied the required host institution conditions have been granted HRB Host Institution Status. A list of these Host Institutions recognised by the HRB at the time of this call going live is included as a PDF and can be downloaded by clicking [here](#).

Note: In order to be eligible to apply for funding, an Institution must have been approved as a HRB Host Institution **no later than two calendar months** before the closing date of a call, only pre-approved Host Institutions will appear in this list. If you wish to propose a Host Institution which is not on the HRB list you are advised to contact the HRB at gemshelp@hrb.ie.

Signatory Notification (within Host Institution)

Once the **Host Institution** is selected at the initial stages of application creation, this will allow the Lead Applicant to notify the **authorised signatory** (Dean of Research or equivalent person authorised to endorse research grant applications for the Host Institution) in that Host Institution of the Lead Applicant's intention to submit an application to the SDAP 2023. The signatory's details are pre-populated in the system so the applicant just needs to click 'NOTIFY' within GEMS. We recommend that you **notify the Host Institution signatory** of your intention to apply as soon as possible in the application process. The signatory will receive an email from GEMS with the name and email details of the Lead Applicant and if they have any queries or clarifications they can engage directly to resolve them with the Lead Applicant.

The Host Institution signatory must confirm their willingness to participate as Host Institution for the application through GEMS and once they do this a PDF of the application will be available for them to review with a view to them ultimately approving the final version for submission to the HRB.

1 Lead Applicant' details

This section corresponds to Section 1. Lead Applicant, in the SDAP 2023 application.

1.1 Lead Applicant details

The Lead Applicant is asked about their position and status (contract or permanent), and whether they are seeking salary-related costs. Please note that a letter of support from the Host Institution must be provided if the Lead Applicant is on a contract position.

The Lead Applicant's **contact and CV** details (Name, institution, present position, employment history, profession, and ORCID iD) are managed in 'manage my details' section of GEMS and are automatically included in any application created involving that individual.

The lead applicant is asked to list their profession, if they are a member of any professional bodies, their education, previous experience, supervisory experience and ORCID iD.

Note: The HRB is now an ORCID member. Lead applicants are encouraged to include an ORCID iD by updating their GEMS profile under 'Manage my Details' and this will feed automatically into the application form. You have also the option to import your publication record from ORCID iD in addition to PubMed. Please note this is not a mandatory field for submitting your application. For more information and to register please see <https://orcid.org/>.

1.2 Lead Applicant Relevant Funding

You are asked to provide your 5 most relevant funding awards as Principal Investigator or Co-Applicant.

For the purpose of this application form, Funding Record details should be added directly on to the application form and will not be pulled through from the 'manage my details' section of GEMS.

1.3 Lead Applicant Publications

You are asked to include your **5 most relevant publications** to this application.

Publications are automatically included in any application created involving the Lead Applicant Researcher. To update this information, edit the 'My Research Outputs' section on the Home page of GEMS. You can then use the Publication selection tool in the relevant section of the application form to select your 5 most relevant publications for this application.

1.4 Additional evidence of experience and expertise relevant to this application

The Lead Applicant may wish to include any additional experience or expertise that will support their application. If they are also a data controller, the name of the data set(s) they are data controller for should be included. The Lead Applicant may also want to include previous experience of working in collaboration with knowledge users/data controllers/data processors and large datasets to produce research or evidence for health, evidence of how their research outcomes have been translated into areas of policy and/or practice or of links with other researchers (including those from other research disciplines), evidence of Patient Public Involvement in research that they have undertaken, recognised contributions to research for national need (if not apparent from other sections), and roles/responsibilities as a constructive and effective change agent. Please use this opportunity to describe any career gaps in your CV. The word limit is **400 words**.

2 Co-Applicant Details

2.1 Co-Applicant Details

This section corresponds to Section 2. Co-Applicants details, in the SDAP 2023 application.

The Lead Applicant can add up to 10 Co-Applicants to an application by entering their name on GEMS. If the Co-Applicant is already registered on GEMS, the system will find them and will allow the Lead Applicant to select them. Alternatively, a Co-Applicant can be added manually by entering their name and email details. GEMS will send them an email with login details for completing the registration process and will inform them that they have been invited by the Lead Applicant to participate on the application as a Co-Applicant. **Registered Co-Applicants** can decide whether to

accept or reject their participation and **must consent to the application being submitted jointly in their name**. If a Co-Applicant rejects participation on an application the Lead Applicant is informed and may revise the application accordingly. Co-Applicants who accept participation in an application will be able to edit the application. **The system will flag if another user is working on the application form at the same time via a pop-up warning. A member of the applicant team may choose to override this pop-up message and continue to enter data, but it is advisable that they contact the other person directly to avoid losing data when applying the override function.**

Each Co-Applicant can manage their **contact and CV details** (Name, contact information, institution or organisation, present position, employment history, profession, membership details of professional bodies, and ORCID iD) under 'Manage my Details' section of GEMS and this information will be automatically included in any application that involves this individual.

Co-Applicants will be asked to select whether they are a **Researcher, Knowledge User, Data Controller, Data Processor or PPI contributor Co-Applicant** for the purpose of the proposed research. If a Co-Applicants contributes from more than one perspective, please select the dominant role.

Researcher Co-Applicants

Researcher Co-Applicants will be asked to provide additional information in the application form, including their **5 most relevant publications** in peer-reviewed journals, their 5 most **relevant funding record** (past or current grants held, including HRB grants), and their **current position and status** (contract or permanent). For Researcher Co-Applicants holding contract positions who are seeking their own salary, a **Letter of Support** from the Host Institution must also be included.

Host Institution Letters of Support must be provided for (1) all Lead Applicant- in a contract position and (2) Researcher Co-Applicants in a contract position who are seeking their own salary. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre must include the following information; *[Host Institution – insert name] which is the Host Institution of [applicant - insert name] confirms that [applicant - insert name]:*

- (i) holds an employment contract which extends until *[insert date]* or will be recognized by the Host Institution upon receipt of the HRB ILP award as a contract researcher;
- (ii) has a dedicated office and research space/facilities for which they are fully responsible for at least the duration of the award, and
- (iii) has the capability and authority to mentor and supervise the research team. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

Should the award not fund any additional post-graduate students or post-doctorate researchers and the co-applicant researcher is not required to mentor on this award, the HI is not required to endorse point (iii) above.

The Co-Applicant can describe any additional experience or expertise that will provide evidence of their ability to successfully fulfil the role of co-applicant on the proposed project. Please reference if you are the Data Controller for any of the datasets proposed for the project. Please use this opportunity to describe any career gaps in your CV. The word limit is **400 words**.

Knowledge User Co-Applicants

Knowledge User Co-Applicants will be asked to provide additional information regarding **Evidence of expertise and experience in influencing decision making within knowledge user organisation(s)**. A knowledge user is defined as one in a position of authority to influence and/or make data decisions about health policy or the delivery of services and that can act to ensure that the findings of the research will be translated to influence decision making and change within their (or other) organisations.

Knowledge User Co-Applicants will also be asked to highlight their previous and current roles in influencing decision making processes within their organization or other relevant organisations. They should also use this space to highlight their specific experiences and expertise for the Knowledge User Co-Applicant role in relation to the proposed research. The word limit is **300 words**.

Knowledge User Co-Applicants will also be asked to provide information **regarding Additional evidence of experience and expertise relevant to this application**. Knowledge user Co-Applicants may wish to include here any additional experience or expertise that will support the application. For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health, evidence of Patient Public Involvement in your knowledge user role, and roles/responsibilities as a constructive and effective change agent. If they have research expertise/experience. Co-Applicants may wish to include relevant outputs such as publications, funding secured or other outputs. The word limit is **400 words**.

Data Controller Co-Applicants

Data Controller Co-Applicants will be asked to provide additional information including the name of the data set(s) they are data controller for. Data Controller Co-Applicants may wish to include here any additional experience or expertise that will support the application. For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health. If they have research expertise/experience Co-Applicants may wish to include relevant outputs such as publications, funding secured or other outputs. The word limit is **400 words**.

Data Processor Co-Applicants

Data Processor Co-Applicants will be asked to provide additional information including the name of the data set(s) they are involved in processing. Data Processor Co-Applicants may wish to include here any additional experience or expertise that will support the application. For example, they may wish to include any relevant research experience/expertise, previous experience of working in collaboration or links with researchers to produce research or evidence for health. If they have research expertise/experience Co-Applicants may wish to include relevant outputs such as publications, funding secured or other outputs. The word limit is **400 words**.

PPI Co-Applicants

PPI Co-Applicants should provide some information regarding their experience and expertise relevant to this application. For example, they may wish to include relevant experience as a service

user or carer, relevant experience from their personal lives, prior experience in PPI or any other useful background information. The word limit is **400 words**.

2.2 Development of the application

The engagement between applicant team members in advance of submitting the application should be described, in particular the engagement between researchers, knowledge users and PPI Co-applicants (where appropriate) to ensure the relevance of the research question for policy and/or practice. The word limit is **300 words**.

3 Collaborator Details

This section corresponds to Section 3. Collaborator Details, in the SDAP 2023 application.

The Lead Applicant can add up to 10 collaborators per application. Unlike Co-Applicants, the information for Collaborators is not automatically drawn from the 'Manage my Details' section of GEMS but must be entered by the Lead Applicant. The Lead Applicant must enter **contact and CV details** for all Collaborators including name, contact information, institution or organisation, present position, employment history, profession and membership details of professional bodies, **Publications and Funding Record** (if applicable) (five most relevant publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) relevant to this application where the Collaborator has acted as Principal Investigator or Co-Applicant).

In addition, for each Collaborator a signed **Collaboration Agreement Form** must be provided. A template Collaboration Agreement Form is available for download from GEMS. Forms must be completed, signed, dated, and uploaded where indicated on HRB GEMS. Please label each form with the name of the relevant Collaborator. Electronic signatures are acceptable on letters/forms that are uploaded on GEMS.

4 Project Details

This section corresponds to Section 4. Project Details, in the SDAP 2023 application.

4.1 Project Title

You are asked to provide a title that clearly describes the research to which this application is related. This should be descriptive and concise and should reflect the aim of the project. There is a **200 characters** maximum limit.

4.2 Development of a tool

Please indicate if this application proposes the development of a tool, as set out within Section 3 Scope.

4.3 Project Duration

Please indicate the expected length of the proposed project in months (minimum duration of 12 months and maximum duration is 36 months) and the proposed start date. Projects are expected to start on or close to 1 October 2023. Please note, typical duration should be 18-24 months, 36 months

can be requested only where the application includes the development of a tool to make data sets accessible and/or more widely available and/or the development of simulation models.

4.4 Start Date

The earliest start date for Cycle 1 awards is 1 October 2023.

4.5 Project Lay Summary

You are asked to provide a brief summary of the proposed research including the objectives, design, expected outcomes and potential of the findings to answer policy and/or practice-relevant questions through the use of secondary data.

This lay summary is similar to the Project Abstract in that you are asked to describe what you propose to do, why you think it is important and how you are going to go about conducting, analysing and drawing conclusions from the research. The difference is that it needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience. It should not be copied and pasted from elsewhere in the application. The lay summary may be used when providing information to the public with regards to the variety of research funded by the HRB and may be posted on the HRB website. A well-written lay summary will enable peer reviewers, public reviewers and Panel members to have a better understanding of your research application. The word limit is **300 words**.

4.6 Project Abstract

This should be a succinct summary of the proposed research. This structured summary should clearly outline the background to the research, the aims and hypotheses of the project. The objectives of the project and what the work is expected to establish should be described. It provides a clear synopsis of your application and should set the research application in context. The word limit is **300 words**.

Please note that this section of the application form will be used as an overall summary, and therefore, should be a stand-alone section. Any abbreviations used elsewhere in the proposal should be defined here.

4.7 Keywords

Please enter up to **5 keywords** that specifically describe your research project.

5 Project Description

This corresponds to Section 2: Project Description, in the SDAP 2023 Application form.

Please ensure that your application is focused and that sufficient evidence is provided to enable the international peer reviewers and grant selection panel members to reach a considered judgement as to the quality of your research proposal, its scientific merit and the potential impact of the project in an Irish context. Of particular importance is that you clearly highlight the rationale for the proposed research within the Irish context and keeping in mind that the reviewers will not be from Ireland you must clearly state the rationale and how the findings of the study will be used to influence decision making in the knowledge user's organisation(s).

The Project Description must include:

- Research Question
- Current knowledge, Background to the area, Relevance and Knowledge Gap
- Overall Aim
- Objectives and Deliverables (including Gantt chart or alternative)
- Dataset(s) Overview
- Data Governance Overview
- Research Design and Methodological approach
- Public and Patient and Carer Involvement in Research
- Gender Issues in the Research Project
- Risks and Ethical Concerns
- FAIR Data Management
- Impact Statement
- Dissemination and Knowledge Translation Plan
- IP considerations
- Project Management

5.1 Research Question

Please clearly state the research question behind the proposed work. The word limit is **50 words**

5.2 Current knowledge, Background to the Area, Relevance and Knowledge Gap

Describe the background to the research proposal and detail the size and nature of the issue to be addressed. Include evidence from the literature and give references to any relevant systematic reviews. Where available, include a description of any pilot work, professional and consumer consensus studies already undertaken.

Summarise the need for research in this area, and the rationale for the particular lines of research you plan to pursue. Include the importance of the proposed research for Ireland at a national level and in the context of the research priorities or needs of the knowledge users listed in the application. The proposed research should be explicitly linked to the documented evidence needs of the knowledge user organisation.

Describe the anticipated outputs, outcomes and impact of the proposed research, indicating the anticipated timescale for any proposed benefits to be realised. Provide a clear description of the problem to be addressed and explain why it is important and timely, especially in an Irish context. Be aware that the peer reviewers reading your proposal will be based outside of Ireland, so it is important to describe the current healthcare delivery context in Ireland when discussing issues around need, relevance, timeliness and feasibility.

Demonstrate how the proposed research will build on existing research to influence the application of the research findings into the Irish healthcare system.

Explain how the research has the potential to address the knowledge gap within healthcare services or policy and how it will accelerate the translation of the findings to enable evidence informed decision making. The word limit is **1200 words**

NOTE: you are strongly advised to read the Guidance Notes and in particular the assessment criteria when writing this section.

5.3 Knowledge User(s) and Documented Evidence Needs Summary Table

For each Knowledge User you will be asked to add the following:

- Knowledge Username
- Knowledge User Organisation
- Links to documented evidence needs

5.4 Overall Aim

Please state the overall aim of the research project. The word limit is **100 words**.

5.5 Objectives and Deliverables

Please add a minimum of 3 research objectives. Objectives should be SMART (Specific, Measurable, Achievable, Realistic and Time-bound). For each objective, list a subset of deliverables which will be used to monitor progress throughout the lifetime of the award if successful. Objectives/deliverables should be mapped against estimated completion timelines in a Gantt chart, and any milestones highlighted.

The word limit is 60 words for each objective and 150 words for the deliverables.

You must upload a Gantt chart which lists the above objectives and deliverables against the estimated timelines for completion, together with any additional milestones/key dates (e.g., PhD submission). Please note that the preparation and submission of Data Management Plans should also be added as deliverables/milestones of the Programme.

5.6 Data Set(s) Overview

For each dataset you will be asked to add the following: Data Source, Coverage (e.g. Regional, National or International), Population, Data collection design (e.g. Cohort study), Sample Size, Data Type, Data Variables and whether access has been approved by the Data Controller (Yes/No or N/A: dataset is publicly available). Please complete the table provided in the application form, one table for each data set and attachment a letter of support where required.

Dataset Overview Table: Data Set 1 EXAMPLE

Data Source	TILDA
Coverage	National
Population	General population aged over 50 years
Data Collection Design	Cohort Study
Sample Size	8,507
Data Type	Survey Data, Objective health Data
Data Variables	Demographics, Chronic Conditions, Risk Factors, Medications
Data Controller Name	

Access approved by Data Controller (DC)?	DC Co-applicant: Letter of Support uploaded
---	---

Are you linking datasets? Yes/No

(If yes) Which datasets are being linked?

A requirement of this scheme is that data provider organizations **will preferably be** included as co-applicants or collaborators. Please confirm the name of the data controller for the named datasets.

This will not be required where the data controller is a co-applicant, or where they are a collaborator, and access has been specified in the signed collaborator form.

5.7 Data Governance Overview

Please provide the data governance overview by addressing each of the questions asked in the application form.

Please provide the data governance overview by addressing each of the following questions:

- Describe if there any other potential data sources for this proposed research and/or why aggregated data is not sufficient?
- Describe why access to each dataset, the associated variables and the data reference period is necessary to complete this specific study in line with the principle of data minimisation.
- Provide details of the technical and organisational measures and safeguards in place (in both the data provider and researcher organisations) to support governance and transparency and to ensure that the privacy, confidentiality and data protection rights of data subjects is preserved in line with the Data Protection Act 2018²³ and the Health Research Regulations of the 2018 Data Protection Act²⁴.

Examples (not an exhaustive list) of measures and safeguards that can be put in place:

- Clear and transparent data governance processes
- Project approval process by the data provider is fair and transparent
- Practices are in place to ensure that the principles of data minimisation are adhered to
- Systems are in place to consider data quality
- Best practices in data de-identification are applied to protect patient data privacy
- Best practices in data security and management are applied to reduce re-identification and breach risks
- Transparent guidance is developed clarifying acceptable and unacceptable uses of the data accessed (and possible sanctions)

²³ <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/pdf>

²⁴ <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pd>

- A data risk assessment is completed in accordance with the Data Protection Act - Roles and responsibilities of all parties are clearly set out in data agreement/s
- The research project secures all the necessary approvals in line with best ethical practice and the Health Research Regulations

Please provide details of the Data Protection Officer (DPO) in the data provider organisation/s that will ensure that a data risk assessment is conducted in advance of any data sharing, that robust and proportionate safeguards are in place and that all necessary agreements and approvals will be put in place between all parties in compliance with the Data Protection Act.

Do you require a consent declaration from the Health Research Consent Declaration Committee (HRCDC) to use any of the dataset(s) listed above?

Where explicit consent cannot be obtained from individuals whose personal or pseudonymised data²⁵ is being processed as part of a dataset, a consent declaration is required (See Section 9).

(if yes) Can you provide details of the status of this application?

5.8 Research Design and Methodological Approach

Summarise the proposed research plan, providing descriptions of individual work packages and describe how they integrate to form a coherent research application. **Show how your research design will allow you to answer your research question.**

Include details of the general experimental approaches, study designs and techniques that will be used. Include details on all stages of the study design including the choice of data set(s), a description of the data set(s), the variables that will be used, how issues of data quality will be dealt with (for example missing data), rationale for sampling strategy, statistical analysis plan and methods, including power calculations if necessary, outcomes measures and management plans.

The word limit is **4500 words**.

Do you intend to develop new tools, protocols or practices to improve the accessibility of data?
Yes/No

(If yes) Please include a detailed description of the research design and methods used to do this and how this tool will be used to improve future accessibility for research purposes in accordance with good data governance and in compliance with the Data Protection Act/Health Research Regulations. The word limit is **500 words**.

Notes: You are strongly advised to seek advice and input from an experienced **research design and statistics** expert in advance of submitting your application. **Discrepancies and incorrect approaches in this section represent the most common source of feedback in unsuccessful HRB applications.**

Power calculations and sample sizes must be described and justified, and aligned with the study aim, objectives and goals and the context of the study.

²⁵<https://www.dataprotection.ie/sites/default/files/uploads/202009/190614%20Anonymisation%20and%20Pseudonymisation.pdf>

Explain in detail how new techniques and/or or high-risk studies will be managed and suggest alternative approaches should these fail.

Where new methods are being developed, arrangements for establishing validity and reliability should be described. Examples of non-standard questionnaires, tests, etc. should accompany the application or their content be clearly indicated.

Useful links and resources are summarised in Appendix III.

5.9 Iteration of the proposed research

If an iteration of the proposed research been submitted to any HRB award scheme in the last 3 years state the name of the Award Scheme under which the proposed research had been submitted and the year in which it was submitted.

Please briefly describe the changes that have been made to the application. Have the recommendations from the previous peer, panel, or public review you received influenced the changes you have made? The word limit is **500 words**.

5.10 Public and Patient and Carer Involvement (PPI) in the research project

*The HRB recognises that the nature and extent of meaningful public involvement is likely to vary depending on the context of each study. Please note PPI does **not** include the recruitment of study participants in research projects. It also does **not** include work aimed at raising awareness of the public around research, such as media publications of research findings, and outreach activities such as open days in research facilities.*

Useful resources including practical examples of involving members of the public in your research can be found in Appendix III. Please be aware there are PPI Ignite Network offices in some host institutions.

Are you including PPI in your application?

- **If Yes**, please describe all PPI at each stage of the research cycle:
 - Identifying and prioritising the research question
 - Design
 - Conduct
 - Analysis
 - Oversight
 - Dissemination
 - For each stage, please include the purpose of this involvement and where applicable how PPI has influenced/changed what work has been planned.
 - This section should be a succinct summary of public involvement activities. Provide information on the individuals/groups and the ways in which they will be involved. PPI contributors should be representative of the relevant people and communities impacted by the research topic. **Where** members of the public, patients or carers are involved, they should be compensated for their time and contributions; this should be reflected in the project budget.
 - Please ensure to provide more detail in other sections as appropriate.

- **Important:** The PPI section needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience.
- **If No** Please explain why PPI is not relevant to your project.

The word limit is **600 words**.

5.11 Gender issues in the research project

Please note this section is intended to focus researchers on the **research content**, and **not** the gender balance within the research team

- Please identify and explain how you address sex and/or gender issues for this project
- **Are there potential sex (biological) considerations for this research**
- **Are there potential gender (socio-cultural) considerations for this research?**
- If so, outline how sex and/or gender analysis will be integrated in the design, implementation, evaluation, interpretation, and dissemination of the results of the research application.
- If not, you must clearly demonstrate why it is not relevant to the research application; have you done a literature search to confirm this?

Please see [Appendix III](#) for resources on gender and sex considerations in research applications.

The word limit is **400 words**.

5.12 Potential Risks and Ethical Concerns

Please address any potential risk and/or harm to patients or human subjects/participants in the research, if relevant. Please highlight any potential ethical concerns during this study and/or at follow-up stage. Describe any potential ethical concerns that may arise as a result of this research, even if not part of this application, and how you propose to deal with them. If the proposed research includes vulnerable groups, what additional considerations are there for these participants? The word limit is **400 words**.

5.13 FAIR Data Management and Stewardship

Describe the general approach to data management and stewardship that will be taken during and after the projects, including who will be responsible for data management and data stewardship. With the support of data stewards or other data-related services support in the institution (typically library and ICT and digital service, etc) all Applicants should address as much as possible the following points below regarding the management of the research data to be generated and/or re-used during the research project²⁶.

Please consider the FAIR Guiding Principles for scientific data management and stewardship: **Findability, Accessibility, Interoperability, and Reusability**.

²⁶ Wilkinson, M. D. et al. The FAIR Guiding Principles for scientific data management and stewardship. *Sci. Data* 3:160018 doi: 10.1038/sdata.2016.18 (2016).

1. **Data description and collection or reuse of existing data:** (a) What is the type, format and volume of data? (b) How will the data be collected, created or reused?
2. **Documentation and data quality:** (a) What metadata and documentation will accompany the data? (b) Will you make sure globally resolvable unique, persistent identifiers are in use (e.g DOI)? (c) What data quality control measure do you use?
3. **Storage and backup:** (a) How will data be stored and backed up during the research? (b) How will you take care of data security and personal data protection?
4. **Ethical and legal compliance, codes of conduct:** (a) If personal data are involved, how will you manage compliance with legislation on personal data and security? (b) How will you manage legal issues, such as IPR, copyright, and ownership? Which legislations are applicable? (c) Which ethical issues and codes of conduct are there and how are they taken into account?
5. **Data sharing and long-term preservation:** (a) How and when will you share the data? (b) How do you select data for preservation and where will data be preserved long term (e.g. data repository, archive)? (c) What methods or software tools are needed to access data? (d) How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?
6. **Data management responsibilities and resources:** (a) Who (for example role, position, and institution) will be responsible for data management (i.e., the data steward)? (b) What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR?

For this funding call, the initial data management plan is required three months after the start date of the award.

The word limit is **1000 words**.

5.14 Impact Statement

Summarise the impact from the proposed research to the knowledge user organisation(s). Include a clear statement of the relevance of the proposed research to societal health priorities in Ireland and the impact that it will have on national clinical and/or population health and/or health services management.

This statement should be specific and provide information that the external reviewers will find helpful in assessing the potential impact of the proposed research. Impact statements should be written primarily in plain English and cover potential impacts in terms of who will benefit from this research as well as how they will benefit. The word limit is **600 words**.

5.15 Dissemination and Knowledge Translation Plan

The proposed research should be explicitly linked to the documented evidence needs of the knowledge user organisation/s. The question/s must be able to be answered by the research partnership and the application should include a clear and concise knowledge translation plan that will highlight how the research findings will be applied by the knowledge user organisation/s.

Please outline the knowledge translation plan including the processes or steps that will be undertaken to support the uptake of the research findings to influence health and social care policy and/or practice. The knowledge translation plan should include plans for the end of grant diffusion

and dissemination as well as the plans for the processes and steps that will be taken to ensure that the knowledge from the research is not just disseminated but is actively translated to influence policy and/or practice. In addition, the research team should detail how they will assess the impact of the project on the knowledge user organisation(s).

This should include the following: how dissemination strategies will be tailored to meet the needs of stakeholders so the results are of maximum utility; and the planned timeframe and forum for implementation (should results be positive). Applicants are expected to identify and demonstrate how the research findings are likely to enable the healthcare services or policy sector to make informed decisions or valuable changes to its practice, expenditure and/or systems in the short term. In developing the knowledge translation plan, applicants are advised to consider the following questions:

- To what extent will the project have relevant findings that will ultimately have a substantive and sustainable impact on relevant national health outcomes, practice, programmes and/or policies?
- Has an appropriate approach to knowledge translation been taken for the research being proposed, which draws from the current literature in this area?
- To what extent will the project's findings be transferable to other practice, programmes and/or other policy contexts?
- To what extent will knowledge users be involved in interpreting the results and informing knowledge translation plans/activities?
- Are end of grant knowledge exchange and dissemination activities suitable for its goals and target audiences?
- To what extent does the evaluation plan demonstrate how the research team will assess the projects impact?

Indicate how the research outputs you anticipate producing during and after your project will be disseminated, shared, and made openly accessible, in line with HRB Open Access Policy²⁷. Research outputs include peer-reviewed publications, non-peer reviewed publications and conference proceedings, reports, policy briefings, guidelines, training materials and so on.

Protection of Intellectual Property should be considered before data are disseminated²⁸.

Please note the HRB has a mandatory Open Access publication policy; demonstrate how you plan to make all publications open access. Types of publication routes include²⁹:

Green Route: publishing in a traditional subscription journal. Articles are 'self-archived' (added) to a repository (institutional or external subject-based) and usually made available after an embargo period, which is set by the publisher.

²⁷ <http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/>

²⁸ All HRB Host Institutions must subscribe to the National Intellectual Property Protocol, 'Inspiring Partnership- the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland', prepared by Government/Knowledge Transfer Ireland to ensure transparent and consistent procedures for managing Intellectual Property from publicly funded research

²⁹ <https://www.jisc.ac.uk/guides/an-introduction-to-open-access>

Gold Route: publishing in an open access or hybrid journal. Articles' processing charges (APCs) are required so that the article is openly available immediately on publication and can be added to a repository (institutional or external subject-based).

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.

(www.hrbopenresearch.org/).

NOTE: applicants are strongly advised to read the Guidance Notes and in particular the assessment criteria that will be used to assess applications. The word limit is **800 words**.

5.16 IP Considerations

The Lead Applicant together with the Host Institution has a duty to the public to ensure that discoveries and advancements in knowledge arising from any award are translated for public benefit including but not limited to commercial development of new therapies, diagnostics, materials, methodologies, and software for health³⁰. Please consult with the relevant Technology Transfer Office for advice on this section, where appropriate.

Please describe any current Intellectual property (IP) that will be relevant for the study and whether such IP assets are held by the applicants, and/or others outside the research team. Such IP might include software, checklists, scales, protocols, guidelines, questionnaires, or medicinal products for example. Has relevant background IP for your study been identified? If IP is required, is there freedom to operate, such that this research can eventually be translated? What arrangements are in place to manage IP during the study, and ensure it is protected (if appropriate) prior to dissemination? Do you foresee any barriers to use of IP in order for the research outputs to be adopted? The word limit is **300 words**.

5.17 Project Management

Please describe how the research project will be managed. The role of each applicant team member and research personnel member should be clearly outlined. Describe any oversight, advisory or governance structures that are crucial to delivery of the project, including a steering committee or data safety and monitoring committee if applicable. Outline the processes that will be put in place to ensure that the project is well managed, commenting on project management, meetings schedules, financial management etc. Describe contingency plans, including how you intend to manage any risks to the delivery of the project. The word limit is **600 words**.

A **file upload** option is available to include an attachment to support your Project Description. A maximum of 5 figures, which can be a combination of images, graphs, tables, scales, instruments, or surveys, may be uploaded as a single document on HRB GEMS. They must not be embedded within the text of the Project Description. The maximum size is 2MB.

³⁰ National Intellectual Property Protocol, 'Inspiring Partnership- the national IP Protocol 2016: Policies and resources to help industry make good use of public research in Ireland'

5.18 References

A full description of the Publications cited in the Project Description should be provided. You can enter a maximum of 30 publications. Please enter references in the same format. For example, the following format may be used:

Gallagher PA, Shoemaker JA, Wei X, Brockhoff-Schwegel CA, Creed JT. Extraction and detection of arsenicals in seaweed via accelerated solvent extraction with ion chromatographic separation and ICP-MS detection. *Fresenius J Anal Chem.* 2001 Jan 1;369(1):71-80. PMID: 11210234

For book and printed source citations:

Farrell M, Gerada C and Marsden J (2000) External review of drug services for the Eastern Health Board. London: National Addiction Centre

6 Details of the Research Team

This corresponds to Section 6: Details of the Research Team, in the SDAP 2023 Application form

6.1 Lead Applicant Role

Please indicate the current commitment to research/clinical/teaching/other, either as a percentage or a proportion of a full time equivalent (FTE).

Give an outline of the proposed role of the Lead Applicant in this project on a day-to-day basis. Please indicate below the proposed amount of time to be dedicated to working on **this project**, either as a percentage or a proportion of a full time equivalent (FTE). The word limit is **250 words**.

6.2 Co-Applicant Role

For **each Co-Applicant**, please identify the type of Co-Applicant they are here (Researcher Co-applicant, Knowledge User Co-applicant, Data Controller Co-applicant, Data Processor Co-Applicant, or PPI Co-applicant) and outline their role in this project on a day-to-day basis, including the amount of time to be dedicated to working on this project either as a percentage or as a proportion of a full time equivalent (FTE). Up to a maximum of 10 Co-applicants can be included. The word limit is **250 words**.

Note: It is not mandatory to have 10 Co-Applicants but this is to allow for flexibility should this be appropriate.

6.3 Collaborator Role

For each Collaborator, please outline their role in the project. The word limit is **100 words**.

6.4 Personnel

Give full details of all personnel to be funded through this project, including the Lead Applicant if relevant. State the percentage of time each person will spend on the project and describe what aspects of the proposed research they will be involved in over the lifetime of the project.

Note that you must justify the nature of all research personnel relative to the scale and complexity of the project. If funding is requested for known personnel, please include the following details: Name, present position, academic and professional qualifications. The word limit is **400 words**.

7 Infrastructure & Support

7.1 Host Institution Infrastructure and Support

Describe the infrastructure, facilities, specialist expertise and other support available at the Host Institution and/or at other sites where the research will be conducted. Please include details of critical supports in areas such as statistics, research methods, data management or regulatory expertise where this is being provided above and beyond the activities/expertise of members of the research team. The word limit is **400 words**.

7.2 Access to Research Infrastructures

Applications availing of the advice, research design, data management services and/or other forms of support from a research infrastructure are required to provide additional information detailing the scope and nature of the engagement (this includes national facilities and/or international facilities and units/networks where justified) at research design or implementation stages. The following information must be provided:

Name and address of the facility/centre/network.

Information on the nature and stage/s of the input/advice/collaboration/service.

Rationale for the choice of facility/centre/network.

How the proposed involvement enables the planned research to be undertaken to the required quality or timescale.

The word limit is **400 words**.

An **Infrastructure Agreement Form** must be completed and can be downloaded from GEMS. The Form must be completed, signed, dated, and uploaded on GEMS. Electronic signatures are acceptable for letters/forms that are uploaded on GEMS.

8 Project Budget

Please provide a summary and justification of the costs and duration associated with the proposed project.

8.1 Budget justification

A **full detailed breakdown of costings and justification for all funding** is required for items listed under each subheading within GEMS.

Note: You are strongly advised to seek guidance from the research office/finance office in the Host Institution before completing this section of the form. The HRB will not provide additional funding in the case of either under-estimates or over expenditure.

The total HRB funding available will be a maximum of €250,000 over 18-24 months (36 months if application includes the development of a tool to make data sets accessible and/or more widely available and/or the development of simulation models).

Funds	Details
1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	<p>Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with Host Institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scales for academic researchers http://www.iua.ie/research-innovation/researcher-salary-scales/.</p> <p>Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure.</p> <p>Applicants should include annual pay increments for staff and related costs (pension contribution, employer’s PRSI contribution, and overhead contribution) in the budget.</p> <p>Salaried researchers who are registered for a PhD degree (e.g., clinical fellows) are expected to have a contribution to gross salary costs (inclusive of employee’s pension contribution) up to a maximum amount of Level 3, Point 1 of the most up to date IUA scale.</p> <p>In line with the proposed new pay agreement for State employees please apply a salary contingency of 2% from 1st October 2023 onwards. Please note this contingency should be applied cumulatively year on year.</p> <p>Note: The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators</p>
b) Employer’s PRSI	Employer’s PRSI contribution is calculated at 11.05% of gross salary.
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 and note the % of 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 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.</p>
2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, PPI costs etc.

	<p>Access to necessary special facilities or services which are not available in the host academic or clinical institutions. will be considered under running costs as long as they are detailed in an accompanying ‘Infrastructure Agreement Form’.</p> <p>Costs associated with compensating PPI contributors involved in your research e.g., consultation workshops, time spent reviewing material, costs of participation in advisory groups, travel expenses, payments for time (in line with your Host institutions policies), etc. should be charged to running costs.</p> <p>Any training costs must be linked explicitly to the objectives of the SDAP scheme.</p> <p>Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.</p>
3. Equipment	<p>Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €10,000. Personal/Stand-alone computers <u>will not</u> 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, and should not exceed €1,200. All costs must be inclusive of VAT, where applicable.</p>
4. Dissemination Costs	<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 detailed in the dissemination and knowledge translation plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research³¹. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary).</p> <p>Publications: Typically, the average HRB contribution towards publication costs is €1,750/per article or 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. (www.hrbopenresearch.org) free of charge.</p> <p>Conferences: We envisage that conference costs will be typically around €500/year for national conference and €1,500/year for international conference.</p>
5. FAIR Data Management Costs	<p>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. Please see table below for further guidance.</p>
6. Overhead Contribution	<p>In accordance with the HRB Policy on Overhead Usage³², 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 fees, equipment, and capital building costs) for laboratory or clinically based research and 25% of Total Direct Modified Costs for desk-based research.</p>

³¹ <http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/>

³² <http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-usage-of-research-overheads/>

	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.
7. Co-Funding Contribution	Please include details of any co-funding committed by the knowledge user organisation. Note: This is not a mandatory application requirement.

Additional guidance to FAIR Data Management Costs

People	Staff time per hour for data collection, data anonymisation, etc Staff time per hour for data management/stewardship support, training, etc
Storage and computation	Cloud storage, domain hosting charge
Data access	Secondary data access, costs for preparing data for sharing (e.g., anonymisation)
Deposition and reuse	<ul style="list-style-type: none"> Costs for depositing research data and metadata in an open access data repository Defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please further explain
Notes	<ul style="list-style-type: none"> - The HRB is currently not covering the cost of long-term preservation of data - This list is not exhaustive and aims to provide examples only of eligible costs

8.2 Co-Funding Budget Commitment

If applicable, please include details on any co-funding commitment from the knowledge user organisation/s and indicate the total amount secured from this Co-Funding.

Note: The contribution listed here should also be included in the full budget section of the form under the co-funding contribution section

Co-Funding Commitment Letter

Please note that a Co-Funding Commitment Letter must be uploaded where co-funding is part of this application. This letter should confirm that the funding contribution is in place. It is not a mandatory application requirement to secure co-funding.

8.3 Other Funding

Please indicate if you have submitted this, or a similar application, to another HRB scheme or funding body. If this application has been submitted elsewhere, please indicate which HRB scheme or funding body, project title, result of submission or when outcome is expected and the amount of award. The word limit is **300 words**.

Give details of any other financial support or In-Kind support for this project that has not been included in the co-funding section. Indicate the project title, the organisation providing the additional

support, the amount of support and the activities that it will support. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review. The word limit is **400 words**.

9 Ethical Approval

Ethical approval is required for all research work funded by the HRB that involves human participants, human material (including tissue) or animals (pre-clinical models only). 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 such approvals must be submitted to the HRB before the initiation of the award. It is suggested that these are sought in parallel to the submission of the application to the HRB.

Submission of Applications

Please note that this is a rolling call and as such there will be one call with two separate closing dates with staggered deadlines and distinct rounds of peer review. Applicants should only apply to one Cycle in the SDAP 2023 call. Applicants that have submitted a proposal for Cycle 1 will not be able to submit the same* proposal for Cycle 2. They will be able to submit a different proposal but should do so only in the event that they will be able fulfil commitments to both research proposals should both be successful.

*For Cycle 2 applications that were unsuccessful in Cycle 1 will only be accepted where there have been significant **substantive changes** incorporating previous peer and panel review feedback.

The deadlines for submission of complete applications are:

Cycle 1 deadline: 15 December 2022 @ 1pm

Cycle 2 deadline: 04 October 2023 @1pm

1. After successful validation, the Lead Applicant may submit the application. It will then be routed to the designated signatory at the Host Institution for their approval.
2. If a signatory rejects the application the Lead Applicant will be notified, along with any feedback the signatory has supplied.
3. The application can then be re-submitted; it will be returned to the signatory and will continue through the approval process as before.
4. On completion of the final approval by the Host Institution signatory, a grant application number is assigned to the application.
5. The application automatically gets submitted to the HRB through GEMS for consideration for funding.

Please note that the HRB will not follow up any supporting documentation related to the application, such as Host Institution's Letters of Support, Collaborator Agreement Form, Gantt charts etc. It is the responsibility of the Lead Applicant to upload all supporting documentation prior to submission. If the documentation is not received by the HRB on time, in the correct format

or is not properly signed or submitted, the application will be deemed ineligible without further review.

The HRB reserves the right to reject any application that does not meet the terms of this call. The HRB's policy on ineligibility decisions is available at [Appealing ineligibility decisions in funding schemes \(hrb.ie\)](#).

Appendix II: HRB Funding Policies and Procedures

Access and support from research infrastructures

Applications availing of the advice, research design, data management services and/or other forms of support from a Clinical Research Facility/Centre (CRF/CRC), other infrastructure (e.g., Centre for Applied Medical Imaging, CAMI, Centre for Support and Training in Analysis and Research (CSTAR), HRB-TNRN, Cancer Groups, National clinical trials office (NCTO), CTNs or a biobank) are required to provide additional information detailing the scope and nature of the engagement (this includes national and international facilities, Units, and networks where justified).

An Infrastructure Agreement form will be requested as part of the application addressing the nature/scope of the service or collaboration, the rationale behind the choice of facility/centre/network and any costs associated with the project (including those provided as in-kind contributions). Applications proposing research with patients which do not detail advice and/or support from a CRF/CRC/CTU will be asked to justify why they have not done so.

Public, Patient and Carer Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public, patients and carers in the research that we fund³³. Public and patient involvement in research means that the public and patients are involved in planning and doing research from start to finish and help tell the public about the results of research. PPI, as defined here, is distinct from and additional to activities which raise awareness, share knowledge, and create a dialogue with the public, and it is also distinct from recruitment of patients/members of the public/carers as participants in research.

PPI represents an active partnership between members of the public, patients and carers and researchers in the research process. This can include, for example, involvement in the selection of research topics, assisting in the design, advising throughout or at specific decision points of the research project or in carrying out the research.

PPI contributors should be actively involved and part of decision making. Involving members of the public in research can improve quality and relevance of research. It can:

- Provide a different perspective - even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition.
- Help to ensure that the research uses outcomes that are important to the public.
- Identify a wider set of research topics than if health or social care professionals had worked alone.
- Make the language and content of information such as questionnaires and information leaflets clear and accessible.
- Help to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants.

³³ <https://www.hrb.ie/funding/funding-schemes/public-and-patient-involvement-in-research/>

Help you increase participation in your research by making it more acceptable to potential participants.

In addition to improving relevance and quality of research, it ensures that research is influenced by broader principles of citizenship, accountability, and transparency. PPI is an ethos as well as a practice. It should be context-specific and should aim to ensure that all voices are heard. Where members of the public, patients or carers are involved, they must be compensated for their time and contributions.

In the application, you are asked to describe any public involvement in your research throughout the various stages of identifying and prioritising the research question, the research design, conduct, analysis, and dissemination. We recognise that the nature and extent of active public involvement is likely to vary depending on the context of each study or award. PPI contributors should be named as Co-applicants where justified by their level of involvement.

For guidance and support on PPI in your research please consult with the PPI Ignite Network Ireland or your Host Institution. The PPI Ignite Network Ireland has offices located in the following seven Host Institutions: DCU, NUIG, RCSI, TCD, UCC, UCD, UL.

FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support [open research](#)³⁴ and open publishing directly through the [HRB Open Research platform](#)³⁵. The HRB is driving the making of research data **FAIR** (Findable, Accessible, Interoperable and Re-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles³⁶ 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.

In line with the HRB's policy on management and sharing of research data³⁷, all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three months after the award start date, and a final updated version of the DMP with the last annual report.

The DMP will need to be submitted alongside a certification of completion from the designated representative(s) within the Host Institution.

Applicants will have to provide an outline of their plans for data management and data sharing in the application

³⁴ <http://www.hrb.ie/funding/policies-and-principles/open-research/>

³⁵ <https://hrbopenresearch.org/>

³⁶ <https://www.nature.com/articles/sdata201618>

³⁷ https://www.hrb.ie/fileadmin/user_upload/HRB_Policy_on_sharing_of_research_data.pdf

The timing for completion and submission of the DMPs must be also included among the objectives and deliverables of the programme.

General Data Protection Regulation

The **General Data Protection Regulation** (GDPR) came into force on 25 May 2018. As a result, the applicant team will be asked through the HRB online grant management system GEMS to **confirm you understand** that personal data provided as part of this application, including but not limited to CV information, may be shared with person(s) based outside of the European Economic Area (EEA) for the specific purpose of obtaining peer reviews of this application. International reviewers play a vital role for the HRB in setting standards and in benchmarking our scientific community to enable them to operate in a global context. Individual peer reviewers are selected for their specific expertise in relation to submitted applications and can be based anywhere in the world.

Furthermore, by confirming participation, you will be asked to confirm you understand that HRB uses the information you provide (regarding all applicant team members) to consider your application, contact you about your application, and if you are successful, 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.

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)³⁸ 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 Committee³⁹.

³⁸ <http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf>

³⁹ <https://hrcdc.ie/>

Research on Research

The HRB is developing its approach to research on research (RoR) with the aim of enhancing the evidence base for HRB research funding practices. We may also collaborate with researchers on request regarding specific RoR questions. Should your application become of interest to such a study, the HRB will seek your consent for the use of your information.

Conflict of Interest

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

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

Appeals procedure

The HRB's procedure for appealing ineligibility decisions in funding schemes is available at <https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/appealing-ineligibility-decisions-in-funding-schemes/>

The HRB's procedure for appealing funding decisions is available at <http://www.hrb.ie/funding/funding-schemes/before-you-apply/relevant-policies/>.

Privacy Policy and Retention Policy

To understand why we collect the information we collect and what we do with that information, please see our Privacy⁴⁰ and Retention Policies⁴¹.

⁴⁰ <https://www.hrb.ie/about/legal/privacy-policy/>

⁴¹ https://www.hrb.ie/fileadmin/user_upload/HRB_Document_retention_policy..docx

Appendix III: Resources/Useful Links

Knowledge Translation and Resources

Health Service Executive Research & Development Main Page

<https://hseresearch.ie/research-dissemination-and-translation/>

Health Service Executive Research & Development: Knowledge Translation, Dissemination, and Impact A Practical Guide for Researchers

<https://hseresearch.ie/wp-content/uploads/2021/04/Tools-and-templates-.pdf>

Integrated Knowledge Translation (iKT) NUI Galway

<https://www.nuigalway.ie/hbcrg/ikt/>

The Canadian Institutes of Health Research: Guide to Knowledge Translation Planning

<https://cihr-irsc.gc.ca/e/45321.html>

Training Institute for Dissemination and Implementation Research in Health: Open Access Course

<https://cancercontrol.cancer.gov/is/training-education/TIDIRC-open-access>

Implementation Science Resources

Centre for Effective Services

<https://www.effectiveservices.org/resources/implementation>

UCC Implementation Science Training Institute

<https://www.ucc.ie/en/cpd/options/medhealth/cpd1778uccimplementationsciencetraininginstitute/>

European Implementation Collaborative

<https://implementation.eu/resources/>

Co-Creation Resources

ACCOMPLISSH Guide to impact planning

<https://www.accomplish.eu/publications-and-deliverables>

Working together to co-create knowledge: A unique co-creation tool – Carnegie UK Trust

<https://www.carnegieuktrust.org.uk/publications/working-together-to-co-create-knowledge-a-unique-co-creation-tool/>

HRB Data Collections & Evidence

HRB Data Collections & Evidence: Alcohol and drug treatment:

<https://www.hrb.ie/data-collections-evidence/alcohol-and-drug-treatment/>

Alcohol and drug deaths:

<https://www.hrb.ie/data-collections-evidence/alcohol-and-drug-deaths/>

Disability service use and need:

<https://www.hrb.ie/data-collections-evidence/disability-service-use-and-need/>

Psychiatric admissions and discharges:

<https://www.hrb.ie/data-collections-evidence/psychiatric-admissions-and-discharges/>

HRB Evidence Centre:

<https://www.hrb.ie/data-collections-evidence/hrb-evidence-centre>

International Collections:

UK biobank:

<https://www.ukbiobank.ac.uk/>

British Cohort Study:

<https://cls.ucl.ac.uk/cls-studies/1970-british-cohort-study/>

National Child Development Study:

<https://cls.ucl.ac.uk/cls-studies/1958-national-child-development-study-2/>

Longitudinal Study of Young People in England:

<https://www.gov.uk/government/publications/longitudinal-study-of-young-people-in-england-cohort-2-wave-1>

English Longitudinal Study of Aging:

<https://www.elsa-project.ac.uk/>

Understanding Society:

<https://www.understandingsociety.ac.uk/>

British Household Panel Survey:

<https://www.iser.essex.ac.uk/bhps>

Global Burden of Disease:

<http://www.healthdata.org/gbd/dat>

Reporting

COMET (Core Outcome Measures in Effectiveness Trials) Initiative: development and application of agreed standardised sets of outcomes, known as ‘core outcome sets’

<http://www.comet-initiative.org/>

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies

<https://www.equator-network.org/library/>

Registry of Research Data Repositories

<http://www.re3data.org/>

Zenodo Data Repository (OpenAIR)

<https://zenodo.org/about>

<https://zenodo.org/>

Evidence Synthesis

Evidence Synthesis Ireland: aims to build evidence synthesis knowledge, awareness and capacity among the public, health care institutions and policymakers, clinicians, and researchers on the Island of Ireland. <https://evidencesynthesisireland.ie/>

The Cochrane Library: online collection of databases in medicine and other healthcare specialties which summarise and interpret the results of medical research. www.thecochranelibrary.com

The Campbell Collaboration: promotes positive social and economic change through the production and use of systematic reviews and other evidence synthesis for evidence-based policy and practice. <https://www.campbellcollaboration.org/>

The Campbell Collaboration UK & Ireland: hub at Queens University Belfast. <https://www.qub.ac.uk/research-centres/CampbellUKIreland/>

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies. <http://www.equator-network.org/resource-centre/library-of-health-research-reporting/>

Public, Patient and Carer Involvement in Research & Research Priorities

The National PPI Ignite Network
<https://ppinetwork.ie/>

NIHR PPI resources
<https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437>

Patient-Centred Outcomes Research Institute (PCORI)
<http://www.pcori.org>

Public Involvement Impact Assessment Framework: Provides tools for successful involvement of members of the public in research projects and for assessment of impacts. <http://piiif.org.uk/>

NIHR Payment guidance for researchers and professionals
<https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392>

European Patient Forum Value + Handbook: For Project Co-ordinators, Leaders and Promoters on Meaningful Patient Involvement. http://www.eu-patient.eu/globalassets/projects/valueplus/doc_epf_handbook.pdf

The James Lind Alliance Priority Setting Partnerships: Research priorities in disease areas set jointly by patients, clinicians, and researchers. <http://www.jla.nihr.ac.uk/>

Campus Engage: Supporting Irish HEIs to embed civic engagement in their work. Includes resources, how-to-guides, and case studies for engaged research. <http://www.campusengage.ie/what-we-do/publications/>

UK Standards for Public Involvement: The six UK Standards for Public Involvement provide clear, concise statements of effective public involvement against which improvement can be assessed.

<https://sites.google.com/nih.ac.uk/pi-standards/home>

Gender and/or Sex Issues in Research

Examples of case studies in Health & Medicine where gender/sex in research matters

<http://genderedinnovations.stanford.edu/case-studies-medicine.html>

Gender Toolkit in EU-funded research for examples and guidance

http://www.yellowwindow.be/genderinresearch/downloads/YW2009_GenderToolKit_Module1.pdf

Sex/Gender Influences in Health and Disease

<https://orwh.od.nih.gov/sex-gender/sexgender-influences-health-and-disease>

Methods and Techniques for Integrating Sex into Research

<https://orwh.od.nih.gov/sex-gender/methods-techniques-integrating-sex-research>

NIH Policy on Sex as a Biological Variable

<https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable>

Data Management and Sharing and FAIR Principles

Digital Curation Centre: How to develop a data management and sharing plan and examples of DMPs.

<http://www.dcc.ac.uk/resources/data-management-plans/guidance-examples>

FAIR data principles FORCE 11

<https://www.force11.org/fairprinciples>

UK Concordat on Open Research Data (July 2016)

<https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf>

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

FAIR at the Dutch centre for Life sciences

<https://www.dtls.nl/fair-data/>

Registry of Research Data Repositories

<http://www.re3data.org/>

Research Data Management Plans

Data Stewardship Wizard created by ELIXIR CZ and NL

<https://dmp.fairdata.solutions/>

DMPonline of the Digital Curation Centre (DCC), UK

<https://dmponline.dcc.ac.uk/>

DMPTool of University of California Curation Center of the California Digital Library (CDL), USA

<https://dmptool.org/>

RDMO Research Data Management Organiser of the German Research Foundation, Germany

<https://rdmorganiser.github.io/en/>

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

Information on Persistent Identifiers

DOI: List of current DOI registration agencies provided by the International DOI Foundation

http://www.doi.org/registration_agencies.html

Handle: Assigning, managing and resolving persistent identifiers for digital objects and other Internet resources provided by the Corporation for National Research Initiatives (CNRI)

<http://www.handle.net/>

PURL: Persistent Identifiers developed by the Online Computer Library Center (OCLC). Since 2016 hosted by the Internet Archive

<https://archive.org/services/purl/>

URN: List of all registered namespaces provided by the Internet Assigned Numbers Authority (IANA)

<https://www.iana.org/assignments/urn-namespaces/urn-namespaces.xml>

Data Repositories

Registry of Research Data Repositories

<http://www.re3data.org/>

Data centers accredited by the German Data forum according to uniform and transparent standards (Germany)

<https://www.ratswd.de/forschungsdaten/fdz>

Zenodo Data Repository (OpenAIR)

<https://zenodo.org/>

Appendix IV: Definitions

Academic Researcher

Academic researchers are individuals from a variety of disciplines who are conducting research and other academic activities in academic or other research performing organisation.

Data controller

A '**controller**' refers to a person, company, or other body that decides how and why a data subject's personal data are processed. If two or more persons or entities decide how and why personal data are processed, they may be 'joint controllers', and they would both share responsibility for the data processing obligations⁴². Data Controllers from the provider organisation should be named as Co-applicants where justified by their level of involvement. Otherwise, they should be named as Collaborators unless the exceptions in Section 4.1 apply (the dataset is publicly accessible, the CSO has given a letter of comfort, or the access process will not commence prior to securing research funding).

Data processor

A '**processor**' refers to a person, company, or other body which processes personal data on behalf of a controller. They don't decide how or why processing takes place, but instead carry out processing on the orders of a controller.

Health and care practitioner

Health and care practitioners are individuals providing clinical care including medics, allied health professionals, dentists, nurses and midwives and pharmacists.

Knowledge user

A **knowledge user** is defined as one in a position of authority to influence and/or make decisions about health policy or the delivery of services and can act to ensure that the findings of the research will be translated to influence decision making and change within their (or other) organisations. This is typically managers, policy makers, clinicians, health professionals or others who are in a position to make significant changes to policy or practice. Knowledge user organisations may be Government departments, HSE, other agencies, hospitals or hospital groups, community healthcare organisations, local government, voluntary organisations, research charities, patient/consumer groups or other organisations involved in making decisions regarding the management, structuring and/or delivery of practice or policy in the Irish health and social care system.

⁴² <https://www.dataprotection.ie/sites/default/files/uploads/2019-07/190710%20Data%20Protection%20Basics.pdf>