HRB evidence synthesis award to support clinical practice guideline development (ESCG) 2024

Guidance Notes

Guidance Notes

Key Dates & Times	
Application Open	02 August 2023
Application Closing Date	26 September 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.*

Table of Contents

1 Introduction

Clinical Practice Guidelines (CPGs) produced by local, national and international organisations have a range of common purposes: they include statements that establish best practice standards, provide benchmarks for clinical audits, strive toward improving the quality of healthcare delivery at an organisational level, and provide guidance on particular clinical practices[1]. They are intended to improve the quality of care provided to patients while containing healthcare costs and reducing variability in clinical practice. They offer a way of bridging the gap between what is known to be best evidence and the implementation of best practice standards in healthcare.

A recent review of clinical practice guideline development practices[1] found that regions and/or countries typically establish a working party (referred to using different terminologies such as a guideline panel, guideline committee, guideline development steering committee), to prioritise relevant health topics and to ensure that robust methodological approaches are progressed to identify, appraise, synthesise and describe the evidence-base underpinning best practice recommendations. Leading countries have a solid evidence support infrastructure dedicated to the production of high-quality CPG from the best available evidence, which become national and international benchmarks.

In Ireland, the National Clinical Effectiveness Committee (NCEC) is a Ministerial committee set up in 2010 as a key recommendation of the report of the Commission on Patient Safety and Quality Assurance (2008). The NCEC is supported by the Clinical Effectiveness Unit (CEU) in the Department of Health (DOH). NCEC's mission is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service user care. The NCEC has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and clinical audit so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines and National Clinical Audit.

A core principle of NCEC is to support evidence based, cost-effective clinical care guidelines. Guidelines, which are developed by Guideline Development Groups (GDGs), must be based on the best available evidence and specialist technical and research supports are needed to ensure that evidence is trustworthy and unbiased. GDGs rely on specialists with expertise in areas such as systematic review of clinical effectiveness and/or cost-effectiveness evidence, budget impact analysis and other evidence synthesis methodologies to inform guideline development, implementation and updating. Further details on the interaction between the NCEC, CEU and GDGs, and how the evidence support function operates in practice can be found in Appendix 2.

The Health Research Board (HRB) Strategy (2021-2025)[2] sets out a lead role for the HRB to promote and support national and international evidence review and synthesis activities in order to build capacity, address knowledge gaps, inform guidelines and provide guidance to policy-makers and practitioners. The research and activities supported by HRB contribute to the 'evidence ecosystem' at many different levels and in many different formats, including through building capacity and expertise in relevant methodologies. Examples of HRB supported components of the evidence ecosystem include in-house evidence synthesis activities of the HRB Evidence Centre to inform DOH

[1] https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08975-3

[2] https://www.hrb.ie/strategy-2025/

policies; data and evidence compiled by the HRB National Health Information Systems Unit to inform healthcare policy and planning; evidence generated by HRB funded projects and programmes; and capacity-building in evidence synthesis expertise and methodologies via Evidence Synthesis Ireland (ESI; co-funded by HRB and the Health and Social Care R&D Division of the Public Health Agency Northern Ireland).

From a guideline development perspective, the HRB has funded evidence synthesis to support the work of the NCEC, the CEU and GDGs since 2016 the through the Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER). By mid-2023, 30 National Clinical Guidelines have been added to the suite of National Clinical Guidelines with various HRB-funded evidence synthesis inputs to guideline development. Such inputs have included systematic reviews of clinical effectiveness and/or cost-effectiveness evidence; preparation of budget impact analyses; training and methodology support for GDGs; and systematic reviews on guideline methodologies to clarify the evidence base and to support NCEC processes.

The NCEC and the DOH is currently considering how to promote and ensure that the NCEC and clinical effectiveness functions can ensure evidence based, cost-effective care in Ireland given the changes and challenges in healthcare delivery seen in recent years and the increased demand for evidence. The NCEC Terms of Reference[3], and the suite of NCEC National Clinical Guidelines is under review, with many guidelines due for update and / or retirement.

As part of this broader analysis to ensure that the evidence requirements are future-proofed and responsive to a changing environment, the HRB is launching a call to ensure that high quality evidence support is provided to inform guideline development, while also taking stock of learnings over the last seven years. Such learnings include the need for robust and timely evidence, the evolution of approaches such as 'living evidence'[4], and the importance of advancing national evidence synthesis activities in a global context to share learnings and resources, reduce duplication and research waste, and to advance common goals.

1.1 Aim and Objectives

The aim is to support one award for a period of four years to ensure expert and dedicated evidence support is available to GDGs working on NCEC prioritised topics. The successful applicant team will be expected to:

- Implement annualised programmes of work to provide technical and scientific support to CEU/GDGs on issues relating to evidence synthesis, economic modelling and budget impact analyses in guidelines (including updates to, or retirements of same) prioritised by the NCEC.
- Do this in accordance with NCEC methodology and requirements.
- To communicate evidence outputs to the CEU/GDGs in ways that optimise accessibility and use by GDGs.
- To provide training in evidence synthesis and economic modelling for guideline development to GDGs.

[3] https://www.gov.ie/pdf/?file=https://assets.gov.ie/11492/87f7550e1a21410a96da37d4aecf7ce6.pdf#page=null

[4] https://www.nature.com/articles/d41586-021-03690-1

- Provide advice and support to NCEC and CEU on evidence synthesis methodologies, approaches, tools and resources to inform improvements and innovations in NCEC approaches.

In addition to delivering on NCEC priorities, the team is also expected to have an outward focused mindset, building capacity and driving innovations in the broader evidence support and methodological research community and to:

- Forge alliances and partnerships both nationally and internationally to reduce duplication and enhance coordination, to explore synergies, to collaborate on common agendas and to share learning and best practices.
- Provide training in evidence synthesis and economic modelling for guideline development to wider stakeholders, e.g., other HSE GDGs or agencies, and the evidence synthesis and research methodology community.
- Advance high-quality methodological research relevant to evidence synthesis and economic modelling for guidelines, to inform national and international evidence-based practice.
- Contribute to a register of research gaps identified during evidence synthesis and appraisal, in discussion with other evidence intermediaries and support units (e.g. Evidence Synthesis Ireland, HRB Evidence Centre, NCCP guideline team) and disseminate to relevant stakeholders.
- To develop a fit for purpose website and blended dissemination strategy to promote the work to various audiences and to provide access to outputs (e.g., protocols, handbooks and methodological guidance publications).

2 Scope of Call

This is an open competitive call for proposals that should bring together the appropriate mix of expertise in evidence synthesis and related activities to effectively support the work of the NCEC/CEU, while maintaining an outward focus on the broader evidence ecosystem both nationally and internationally.

Applications should be made by a multidisciplinary and specialist team led out of a host institution in Ireland comprising partnerships with national and external collaborators, as required, to deliver on the aim and objectives.

Required reviews and projects will be of varying scope and size, and therefore duration, depending on the topic under consideration. It is expected that these will include: high-quality systematic reviews, meta-analyses, health economic evaluations and budget impact analyses. While activities will be scheduled according to an agreed work plan, a minimum capacity to work concurrently on 3-4 topics is typically required and should be planned for in the application.

From a governance and operational perspective, the team will be expected to work closely with the CEU via the Executive Committee (See Appendix 2) to agree and provide updates on annual programmes of topics, with the lead applicant expected to participate as observer on the NCEC. More detail on how the evidence support function operates in practice is provided in Appendix 2.

In addition to NCEC support, the proposed programme of work should position the team to engage internationally to ensure it is at the forefront of best international practice when it comes to evidence-informed decision making. It should facilitate sharing of tools and resources developed during its activities and contribute to advancing research on relevant methodologies. It should

contribute to education, awareness and training activities in evidence synthesis to ensure synergies and avoid duplication of effort.

The programme should embrace the experience gained by organisations in delivery of services during the COVID-19 pandemic, demonstrating flexibility in approach and a commitment to exploring innovative approaches to meet demands.

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

3 Funding Available, Duration and Start Date

Applicants may apply for funding up to a maximum of **€2.5 million** (inclusive of overheads).

Quality permitting a single award will be funded for a duration of **48 months**.

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

Note: The 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 work programme, and reviewers will thoroughly assess the level of funds and timeframe requested when reviewing the application.

The earliest start date of the Grant is April 2024.

4 Eligibility Criteria

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

4.1 Applicant Team

Applications should be made on behalf of an interdisciplinary team of researchers with the necessary knowledge, expertise and experience in the conduct of high-quality systematic reviews, meta-analyses, health economic evaluations and budget impact analyses. The team members should have complementary expertise and mechanisms to access additional topic-specific expertise, as required. The programme may be ideally suited to a 'virtual centre' reflecting a hub-and-spoke model, capable of harnessing the required skills and expertise across multiple departments, centres and/or institutions.

Co-applicants and collaborators from outside the Republic of Ireland are encouraged where their participation clearly adds value to the programme.

4.1.1 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.

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 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 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.

They **must** show evidence of achievement as an independent researcher in their 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 (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 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.

d) Have experience and expertise working in the area of evidence synthesis and also have experience of working with national bodies such as the DOH and/or Health Service Executive to deliver nationally relevant projects to budget and under tight time-frames.

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.

As signatory of the DORA Declaration[5], the HRB is committed to supporting a research environment where importance is placed on the intrinsic value and relevance of research and its potential impact in society (HRB - Declaration on Research Assessment).

[5] Home | DORA (sfdora.org)

4.1.2 Co-Applicants

A Co-Applicant has a well-defined, critical, and substantial role in the conduct and steering of the proposed research programme. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards their own salary if they are in salaried positions. However, researchers in contract positions can request their own salary, depending on their role and percentage of time dedicated to the research for the duration of the award (**up to a maximum of 10 Co-Applicants can be listed).**

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.

4.1.3 Collaborators

An official Collaborator is an individual or an organisation who will have an integral and discrete role in the proposed research programme and is eligible to request funding from the award when properly justified. Named collaborators may include investigators or organisations from outside the Republic of Ireland, but an individual or organisation should **only** be named as Collaborator if they are providing specific contributions (either direct or indirect) to the activities. A collaborator may provide training, specialist staff time, staff placements, access to data and/or patients, instruments or protocols, industry know-how, or may act in an advisory capacity. Collaborators can come from a range of backgrounds such as 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.

The terms of any collaboration 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, ownership and copyright, access and sharing of data and samples etc. when working up collaboration agreements.

4.1.4 Funded Personnel

Applicants must demonstrate that the level, expertise, and experience of proposed research personnel matches the ambition and scale of the proposed activities 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 activities should be demonstrated. Roles and responsibilities of funded personnel must be differentiated and clear.

Unlike the HRB's research career schemes, this scheme is not framed as a training initiative and is not suitable for students in pursuit of a higher degree.

5 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 HRB award schemes. The **Host Institution for the award is normally that of the Lead Applicant** 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 website[6].

Please note that this call **is not** open to Host Institutions from Northern Ireland.

Host Institution Letters of Support must be provided for **(1) all Lead Applicants in a contract position and (2) 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/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 recognised by the host institution upon receipt of the HRB evidence synthesis award to support clinical practice guideline development 2024 as a contract researcher; (ii) has an independent office and research space/facilities for which they is 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.

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.

6 Application, Review Process and Assessment Criteria

6.1 Grant E-Management System (GEMS)

Applications must be completed and submitted through the HRB online Grant E-Management System (GEMS) (https://grants.hrb.ie/).

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.

[6] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/

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.

6.2 Review Process

International Peer/Panel 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.

An international grant review panel will be convened to review applications. The Panel will be comprised of a Chair and at least three international experts with expertise related to evidence synthesis, including HTA and clinical effectiveness reviews and with knowledge of evolving developments in the global evidence ecosystem.

Step 1 – Written assessment

The HRB will seek written feedback from the Panel Reviewers and from two Public Reviewers.

Peer/Panel Reviewers will focus on the stated assessment criteria for the call and will provide comments as well as a score.

Public Reviewers will only assess the quality of PPI in the application and will provide comments and an overall rating which will be shared with the panel. Public reviewers will not provide a score.

Public Reviewers are asked to comment on the following:

- The Plain English Summary (Lay Summary)
- Public and Patient Involvement as relevant to the proposal
- Dissemination and Potential Impact of the Proposed Work

Both peer and public review comments will not include any reference to the reviewer's identity or their submitted scores or rating.

Step 2 - Applicant Response

Applicant teams will be provided with a time-limited opportunity to respond to peer and public review comments.

Peer review and public review comments will be made available to the Lead Applicant on their GEMS personal page. The Lead Applicant will have 10 working days only to submit their response through GEMS, and the response will be provided to members of the Grant Selection Panel, in advance of the Panel meeting, along with the application, the peer/panel and public review comments and rating.

Step 3 - Panel Meeting

The international grant review panel will meet to discuss the applications. Panel members have access to applications, peer/panel and public reviews and the applicants' response. HRB staff members are present at the meeting to clarify any procedural aspects for the Chair or Panel members and to take notes for the feedback process. Key members of applicant team(s) may be invited to attend part of the meeting to be interviewed by the Panel, addressing any outstanding queries the Panel may have.

The Panel will review the strengths and weaknesses of the application relative to the assessment criteria detailed below. Successful applicants are expected to score well in all assessment criteria.

While PPI is not a stand-alone assessment criterion, it may influence scores under any criterion as relevant to the application.

At the end of the panel meeting, a final score and consensus funding recommendation will be collectively agreed by the Panel.

The Panel may suggest items that require follow up by the applicant team prior to making their final recommendation. Once any outstanding issues have been addressed the Panel recommendation will be submitted to the Board of the HRB for consideration. A summary of Panel Member's comments will be issued to the Lead Applicant following the conclusion of the review process.

6.3 Assessment Criteria

The following assessment criteria will be used to assess applications **by Panel Reviewers**. A successful application will be expected to **rate highly in all criteria**.

The **Criteria for Assessment** of the application are:

- **Team:**
  - Expertise, track record and appropriate skill mix
  - Demonstrated understanding of wider policy context in healthcare
  - Access to topic-specific expertise
  - Evidence of ability to work with a wide variety of stakeholders
  - Demonstrated agility and responsiveness to changing priorities
- **Scientific Quality and Relevance:**
  - Quality and appropriateness of proposed activities
  - Appropriate methodological approach
  - Approach to continuous development and alignment with international best practice
- **Broader impact:**
  - Quality of dissemination and knowledge translation plans
  - Potential to enhance capacity and drive innovation in the broader evidence ecosystem
  - Plans to establish new/strengthen existing collaborations, and contribute to national/international networks
- **Governance and management**
  - Appropriate governance and oversight structures
  - Approach to day-to-day management of programme, operations and resources
  - Feasibility and coherence of work packages
  - Level of institutional support, suitability of environment

Each assessment criterion is weighted equally.

7 Timeframe

Date	
02 August 2023	Call Opening
26 September 2023 @13:00	Call Closing
October 2023	Scientific and public review
November 2023	Applicant response
November 2023	Panel Review Meeting
December 2023	HRB Board Decision
Jan/Feb 2024	Budget negotiations and contracting
April 2024	Earliest start date

8 Contacts

For further information on the **HRB evidence synthesis award to support clinical practice guideline development 2024** contact:

Catherine Gill

Programme Manager: Targeted Programmes

Research Strategy and Funding

Health Research Board

E. cgill@hrb.ie

The HRB reserves the right to reject any application that does not meet the terms of this call. **The HRB's Policy on Appeals on funding decisions is available at https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-appeals/.**

Appendix I: Detailed Guidance on the Application Form

Only registered users of the GEMS system can apply for grants. To submit an online application to the HRB, applicants are required to register at the following address: https://grants.hrb.ie

*Please refer to the **GEMS Technical Guidance Note**[7], available on the left-hand column of your GEMS profile homepage, for further information.*

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 Applicant will be asked to complete a check list of mandatory questions. To access the application form, the Lead Applicant must satisfy the conditions of this check list:

Lead Applicant Eligibility	
I have read the Guidance Notes for the ESCG 2024 call	☑
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 Host Institution to access, review and approve my final application for submission to the HRB through the GEMS system.	☑

Consent	
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 ESCG 2024 Call Guidance Notes.	☑

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:

[7] https://research.ie/assets/uploads/2020/05/CCGT-Grant-Application-System-Technical-Guidance-Notes.pdf

Host Institution

For the purposes of contracting, payment, and management of the award, HRB funds can only be awarded to HRB approved Host Institutions. Please note this call is not open for Host Institutions from Northern Ireland. The Host Institution for the award 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.

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.

Note: 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.

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. 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 Team

1.1 Lead Applicant's Details

Details are requested about the **Lead Applicant** including their position and status (contract or permanent), and their supervisory experience. Please note that a **letter of support from the HI** must be provided if the LA is on a contract position.

The LA'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.** You are asked to select your 5 most relevant publications for this application.

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/.

Publications and Funding Record

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.

You should also include 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.

Additional evidence of experience and expertise relevant to this application

The Lead Applicant can describe any additional experience or expertise that will provide evidence of their ability to successfully lead the proposal. Please use this opportunity to describe any career gaps in your CV. The word limit is **400 words**.

1.2 Co-Applicants

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 over-ride 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.

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 **relevant funding record** (past or current grants held, including HRB grants).

They will also be asked to describe any additional experience or expertise relevant to the application (**400 words)**.

Non-researcher co-applicants (e.g., PPI co-applicants) will not be required to complete publication/funding record however, they will be asked to 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 (Word limit is **400 words)**.

1.3 Official Collaborators

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 LA 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) (5 **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 downloaded 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.

1.4 Details of the research team

You are asked to provide an overview of how you will ensure your Programme team will consist of a suitable mix of people with the appropriate expertise and experience required and how they will work together to achieve the objectives of the proposal.

Q1. Describe the roles, responsibilities, and contributions of all applicant team members including lead applicant, co-applicants and collaborators in delivering the programme. **500 words**

Q2. Describe the roles, responsibilities, and contributions of all team members for whom you are requesting salary from the award. Describe how all objectives can be adequately addressed (i.e., NCEC support AND outward focus) through a team of this composition. **500 words**

Q3. Describe any other in-kind or institutional expertise and supports available not covered by the applicant team, salaried team members e.g., administrative, ICT etc. **400 words**

2 Programme Description

2.1 Programme Title

Please insert a title that accurately reflects the programme of research/activities that you will deliver.

There is a **200 characters** maximum limit.

2.2 Lay Summary

In the lay summary you are asked to describe what you propose to do, say why you think it is important to do so and how you are going to go about it. 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 and initiatives funded by the HRB and may be posted on the HRB website. A well-written lay summary will enable reviewers and Panel members to have a better understanding of your application.

The word limit is **300 words**.

2.3 Keywords

Please enter up to **5 keywords** that specifically describe the proposal.

2.4 Programme Description

Please ensure that your application is focused, and that sufficient evidence is provided to enable the international panel reviewers to reach a considered judgement as to the quality of your proposal, its merit, potential impact, and its feasibility.

Within the national/international context for Evidence Synthesis to inform Clinical Guideline development, describe the proposed **plan to deliver the objectives of the programme set out in the Guidance Notes.** Provide descriptions of individual work packages or activity areas, and how they integrate to form a coherent research application.

For each objective or WP/activity area, list a subset of deliverables which will be used to monitor progress throughout the lifetime of the award if successful.

The word limit is **5000 words**.

Objectives/deliverables should be mapped against estimated completion timelines in a **Gantt chart**, and any milestones highlighted.

2.5 Dissemination and knowledge translation strategy

Within your programme description above, you should have described how you will actively and continuously engage with national and international partners and stakeholders to ensure maximum benefit and impact.

In addition, you are required to describe a multi-faceted dissemination strategy to promote the work to various audiences and to provide access to outputs*. This should include development of a fit for purpose website and branding, and broad dissemination of open access outputs, including peer-reviewed publications to increase the impact and utility of your work. Your dissemination strategy should ensure a broad reach and potential impact beyond informing NCEC guideline development.

Describe how you will increase the visibility and availability of outputs for diverse audiences, outside of formal peer-reviewed publications (e.g., protocols, handbooks, methodological guidance publications, infographics), and how you will ensure visibility of your activity.

*It is important to note that the evidence deliverables submitted to the CEU/DOH to inform each GDG will be published as part of the eventual NCEC National Clinical Guideline. Following publication of the Guideline, the applicant team can engage in wider dissemination activities.

The word limit is **600 words**.

2.6 Governance and Oversight

Consideration should be given to the requirement to interface quarterly with the CEU as part of the Executive Committee (Appendix 2) for the purpose of agreeing annual work programmes and providing updates on same.

Describe the governance and management structures, including any mechanisms for engaging with collaborators and partners or details of any planned advisory structures. List the roles and responsibilities of each governance group (e.g., steering, strategic oversight, advisory, other), and clearly describe how these groups fit together in a complementary way without overlap of duties. Details should be provided for how PPI will be included in the governance structures.

The word limit is **600 words**.

You are asked to upload **an organogram** to support your description.

2.7 Public and Patient 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 the research/activities being carried out.

Where relevant, please describe proposed public and patient involvement as it relates specifically to the grant funded activities i.e., evidence synthesis and related activities.

For each area of involvement please include the purpose of this involvement and where applicable how PPI has or is expected to influence activities/actions.

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. **Where members of the public/patients are involved, they should be compensated for their time and contributions; this should be reflected in the project budget.**

The word limit is **600 words**.

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.

2.8 Equality, Diversity, and Inclusion (EDI)

Please describe how you will take EDI into account in a systematic way as appropriate. Areas to consider include, but are not limited to, the following:

- Considering EDI at question formulation stage
- Deciding on methods to identify and appraise evidence related to diversity of outputs/databases, languages, regions and/or specific populations
- Considering implications for summary of findings (e.g. is data available on recruitment and retention for specific subgroups) or for dissemination of findings
- Interpreting findings related to health equity/EDI as a key part (even to point out lack of data on same) in the discussion section.

The word limit is **600 words**.

2.9 Infrastructure and Support

Describe the infrastructure, facilities, and other support available at the Host Institution and/or at other sites associated with the Programme. Please include details of critical supports where this is being provided beyond the activities/expertise of members of the applicant team.

The word limit is **400 words.**

2.10 Support File

You may include an attachment to support your proposal. 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, **if they add value to the written description**. They must not be embedded within the text of the Programme Description. The maximum size is **2MB**.

2.11 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 publications:

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.

For data citations:

Authors, year, article title, journal, publisher, DOI

Author(s), year, dataset title, data repository or archive, version, global persistence identifier

3 Programme Budget

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

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 funding available will be €2.5M over 48 months. Allowable costs include:

1. Personnel costs	Must be listed for each salaried personnel under each of the following subheadings (a-c):
a) Salary	Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with Host Institution. Applicants should use the IUA website scales

	for the most up-to-date recommended salary scales for academic researchers http://www.iua.ie/research-innovation/researcher-salary-scales/. Please note employee pension contribution of 5% has already been incorporated into the IUA gross salary figure. **Applicants <u>should</u> include annual pay increments for staff and related costs (pension contribution and employer's PRSI contribution,) in the budget.** In line with the proposed new pay agreement for State employees please apply a salary contingency of 3% from 1st October 2024 onwards. Please note this contingency should be applied cumulatively year on year. **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
b) Employer's PRSI	Employer's PRSI contribution is calculated at 11.05% of gross salary.
c) Employer Pension Contribution	Pension provision <u>up to a maximum of 20%</u> of gross salary will be paid to the Host Institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference. Exceptions apply where Circular letter 6/2007 applies. Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.
2. Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, data access costs etc. The following costs are ineligible and will not be funded: training courses/workshops, inflationary increases, cost of electronic journals.
3. PPI Costs	All PPI-related costs for the grant (except salaried personnel), such as but not limited to: • Compensating PPI contributors for their time (for example for time spent reviewing material/ participation in advisory groups) • Travel expenses for PPI contributors • Training in PPI in research • Costs associated with PPI contributors attending conferences or workshops • PPI event facilitator costs • Room hire for PPI events/meetings. • Hospitality for PPI events/meetings • Companionship or childcare costs for PPI contributors while attending events, meetings, etc. **<u>Note:</u>** PPI participants supported by salaries, should be listed and justified under the personnel heading. All costs should be in line with Host Institution policies.
4. Equipment	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.
5. Dissemination Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[8]. Please list dissemination costs under the following categories: publications, conferences, **other activities (expanded as necessary).** **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. **Conferences:** We envisage that conference costs will be typically around €500/year for national conference and €1,500/year for international conference.
6. Overhead Contribution	In accordance with the HRB Policy on Overhead Usage , the HRB will contribute to the indirect costs of the research through an overhead payment of 25% of Total Direct Modified Costs for desk-based research.

4 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.

5 Supporting Documentation

The following documents must be uploaded to complete the application:

Mandatory documents:

- Gantt Chart
- Organogram

If applicable:

- Letter of Support from the HI
- Collaboration Agreement Form(s) – required for all collaborators

[8] http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/

- Project Description Support file - A maximum of 5 figures which can be a combination of images, graphs, tables, scales, instruments, or surveys

Submission of Applications

The deadline for submission of complete applications is 26 September 2023 at 13:00.

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 Appeals on funding decisions is available at https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-appeals/.

Appendix 2: Evidence Supports for Guideline development – how it works

National Clinical Effectiveness Committee

Clinical effectiveness is a set of processes that brings information from national and international research and clinical audit together to identify safe, effective and efficient practices based on the best available data and evidence. The integration of best evidence in service provision, through clinical effectiveness processes, promotes healthcare that is up to date, effective and consistent.

In Ireland, the National Clinical Effectiveness Committee (NCEC) was established in 2010. It is a Ministerially appointed committee with membership drawn from across the healthcare sector. The role of the NCEC is to recommend clinical guidelines and clinical audit to the Minister for Health to become NCEC National Clinical Guidelines (NCGs) and NCEC National Clinical Audit (NCA) and for onward implementation in the Irish healthcare system. In Ireland, clinical effectiveness includes cost-effectiveness and budget impact analysis is required to be considered as part of a clinical guideline or clinical audit.

It does this by prioritising clinical guidelines and clinical audit that are important to national policy and the Irish health system, and by assessing clinical guidelines and clinical audit against criteria to judge that they have been developed robustly in line with national and international best practice criteria. Clinical guidelines and clinical audit that successfully go through these steps are recommended to the Minister for Health through the Chief Medical Officer for endorsement and publication as NCEC NCGs or NCEC NCA.

In addition to the functions relating to NCEC NCGs or NCEC NCA, the NCEC also oversees the development of the National Standards for Clinical Practice Guidance. These standards outline the required criteria for development of policies, procedures, protocols, and guidance across the healthcare system. They are operationalised by the HSE Framework for Policies, Procedures, Protocols and Guidance (PPPGs). The current standards were published in 2015 and work is underway to progress their update.

Clinical Effectiveness Unit

The Clinical Effectiveness Unit (CEU) is a unit within the National Patient Safety Office of the Department of Health. The Unit is under the Office of the Chief Nursing Officer. The Unit acts as the Executive for the NCEC, providing secretariat and support to the Committee and working with stakeholders to progress decisions and agreed actions. The Unit supports the clinical effectiveness and clinical audit agenda through its policy work with key stakeholders across the health and social care services on clinical guidelines and audit. Support is provided to guideline development groups and audit governance groups along the continuum of prioritisation, quality assurance, review, update and policy for implementation. The Unit also co-ordinates and prepare reports and publications.

Guideline Development Group

The Guideline Development Group (GDG) is the group of people who work together as guideline authors. Each GDG is multi-disciplinary, and membership is designed to reflect the range of stakeholders whose professional activities and care will be covered by the guideline. Membership consists of healthcare professionals, technical experts, administrators and patient/carer representatives. The GDG undertakes the process of guideline development, preparing and agreeing a final guideline document for submission to the NCEC. The group works with the CEU to progress the guideline through the 4 steps of the *NCEC*

Framework for Endorsement of National Clinical Guidelines (2015)[9] to achieve endorsement by the Minister for Health as a NCEC NCG. The GDG also undertake the consultation required in advance of submission of a clinical guideline for quality assurance under the NCEC criteria.

Evidence synthesis to support clinical practice guideline development

The aim of the evidence synthesis award is to support a team to independently review evidence and provide scientific support for the development of NCGs, by GDGs over a four-year period from 2024. The successful team will undertake systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines as well as estimating the budget impact of implementing the guidelines. The evidence synthesis team will work closely with the GDGs to ensure that its work informs the development of evidence-based recommendations within the NCGs. The needs of individual GDGs can vary, depending on previous experience and work completed, and access to expertise within the GDG. GDGs can only access the dedicated evidence synthesis team services when successfully prioritised through the NCEC and brokered via the CEU. They key point of contact therefore for the evidence synthesis team is with the CEU and to ensure that this contact is structured and planned, the CEU will establish an "Executive Committee" with the evidence synthesis team.

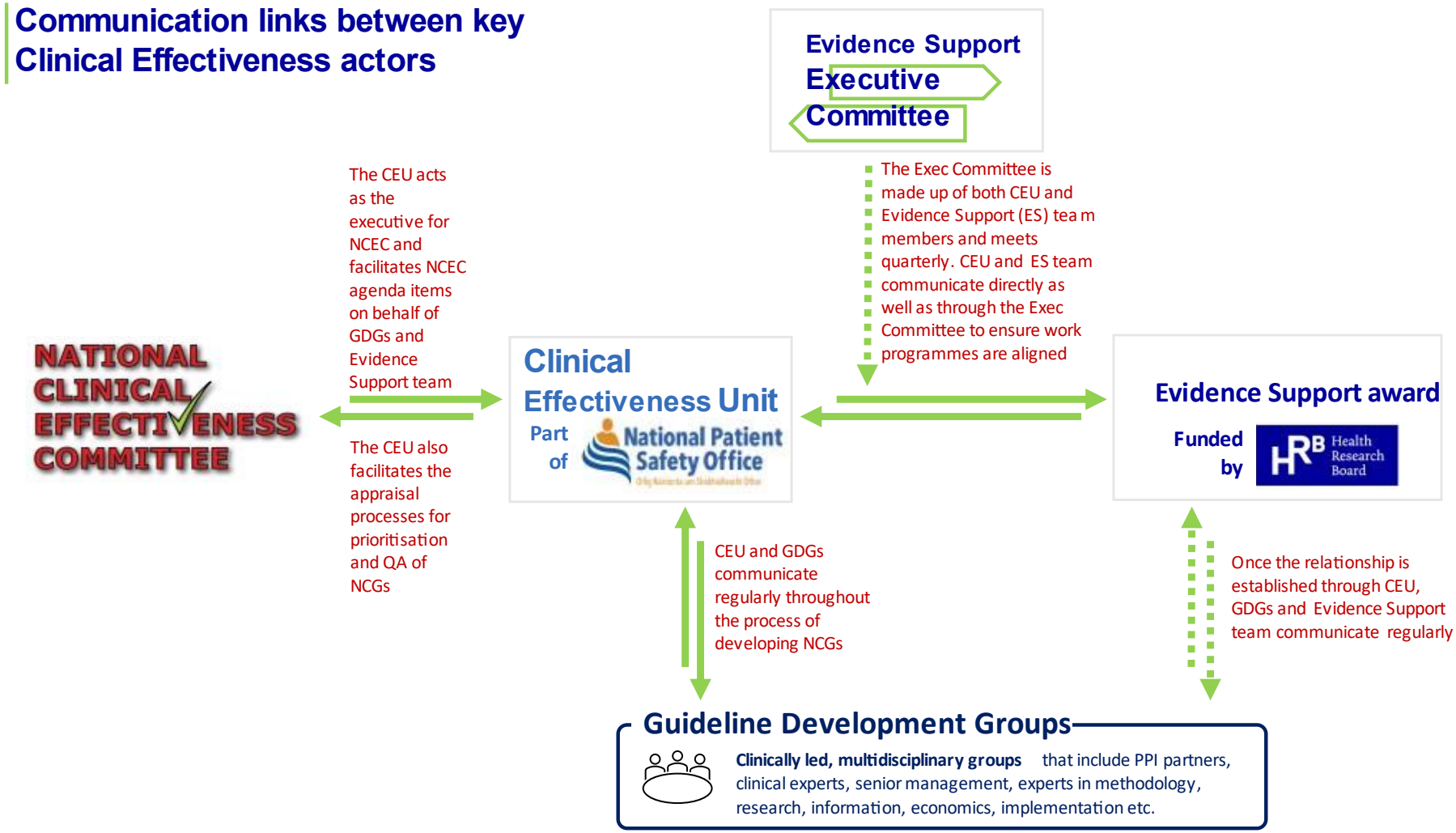
The Executive Committee will meet quarterly and be comprised of membership from both bodies. The role of the committee is to prioritise the work programme of HRB funded evidence synthesis team. It will be responsible for planning a yearly calendar of evidence support according to NCEC priorities and ensuring work programmes are aligned. Evidence Support team activities will be scheduled according to an agreed work plan, but a minimum capacity to work concurrently on 3-4 topics is typically required and should be planned for in the application.

The evidence support team will be required to be responsive to the national clinical effectiveness agenda which is driven by patient safety and clinical programme requirements. Therefore, while the reviews/updates will span areas/topics that will not be known until after the award, the applicant team should identify the process/mechanism through which they will source topic-specific expertise to complement the 'core' research team.

Further information

- NCEC Guideline Development Manual
- Guidance on Budget Impact Analysis of Health Technologies in Ireland
- National Quality Assurance Criteria for Clinical Guidelines Version 2
- National Clinical Effectiveness Committee: Processes and Templates
- Examples of systematic literature reviews and budget impact analysis for NCEC guidelines are available on the NCEC website at: www.gov.ie/clinicalguidelines

[9] e2424b86508c4b928b04cf2770fab528.pdf (www.gov.ie)


Communication links between key Clinical Effectiveness actors
Evidence Support Executive Committee
The Exec Committee is made up of both CEU and Evidence Support (ES) tea m members and meets quarterly. CEU and ES team communicate directly as well as through the Exec Committee to ensure work programmes are aligned
NATIONAL CLINICAL EFFECTIVENESS COMMITTEE
The CEU acts as the executive for NCEC and facilitates NCEC agenda items on behalf of GDGs and Evidence Support team
The CEU also facilitates the appraisal processes for prioritisation and QA of NCGs
Clinical Effectiveness Unit
Part of National Patient Safety Office
Evidence Support award
Funded by HRB Health Research Board
CEU and GDGs communicate regularly throughout the process of developing NCGs
Once the relationship is established through CEU, GDGs and Evidence Support team communicate regularly
Guideline Development Groups
Clinically led, multidisciplinary groups that include PPI partners, clinical experts, senior management, experts in methodology, research, information, economics, implementation etc.