Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER)

Guidance Notes

Key Dates & Times (see below for proposed timelines)	
Call open to applicants	**15 March 2016**
Application closing date	**1 June 2016 @ 1pm**

*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.*

Collaboration in Ireland for Clinical Effectiveness Reviews

Introduction

Clinical effectiveness is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes, promotes healthcare that is up to date, effective and consistent.

The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee established in 2010 as part of the Patient Safety First Initiative. The NCEC is supported by the Clinical Effectiveness Unit (CEU), Department of Health. The NCEC is a partnership between key stakeholders in patient safety and its mission is to provide a framework for national endorsement of clinical guidelines and audit to optimise patient and service user care. The NCEC[1] 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. In its role for prioritising and quality assuring clinical guidelines, the NCEC has defined 'Clinical Guidelines' as:

> "*systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances, across the entire clinical spectrum*"

Clinical Guidelines were one of the Minister for Health's priorities in 2015[2] and guidelines that meet the national prioritisation and quality assurance criteria are recommended by the NCEC to the Minister for Health through the Chief Medical Officer (CMO) for endorsement and implementation. By year end 2015, 14 National Clinical Guidelines were launched with six (including one update) undergoing NCEC processes, and five at Notice of Intent stage. A further five are in early planning/discussions, two updates will be required in 2016/2017 and the pending Maternity Strategy will also make recommendations with regard to developing NCEC clinical guidelines for maternity care.

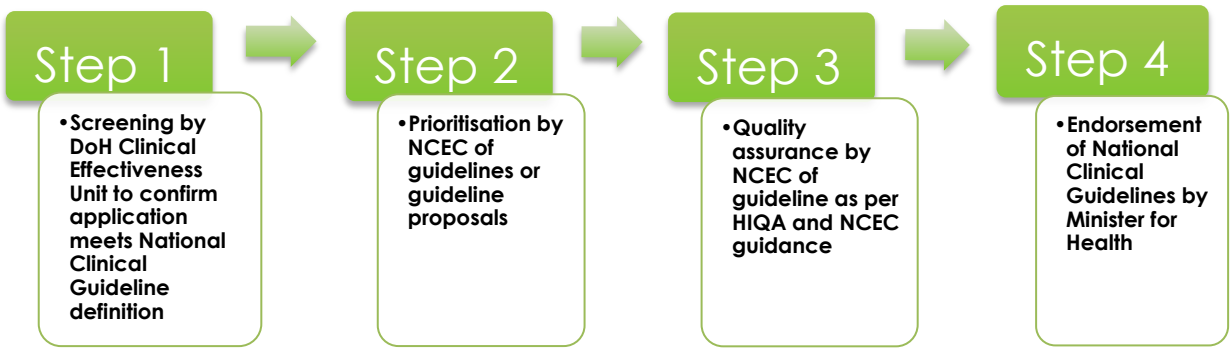
The aim of the suite of National Clinical Guidelines is to provide guidance and standards for improving the quality, safety and cost-effectiveness of healthcare in Ireland. The NCEC draws on international guideline development methodology and the expertise of established Guideline Development Groups (GDGs) where available. The implementation of these National Clinical Guidelines will support the provision of evidence-based and consistent care across Irish healthcare services. NCEC's process for endorsement of National Clinical Guidelines involves a number of steps as outlined in Figure 1.

[1] NCEC Terms of Reference:

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish standards for clinical practice guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and quality-assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
9. Establish sub-committees for NCEC work-streams.
10. Publish an Annual Report.

[2] http://health.gov.ie/blog/press-release/varadkar-lynch-publish-health-priorities-for-2015/

Figure 1: NCEC Framework for Endorsement of National Clinical Guidelines



It is recognised that the NCEC, and the health system as a whole, is likely to be able to effectively implement and monitor only a small number of National Clinical Guidelines each year. Not all clinical guidelines will be submitted for national endorsement and GDGs will continue to develop clinical guidelines in response to the needs of their own organisations. However, once a National Clinical Guideline is endorsed by NCEC it will supersede any other guideline on that topic. The NCEC guidance and tools on guideline development can be used by any clinical GDG regardless of whether they are submitting their clinical guidelines for national endorsement. NCEC documentation and resources are reviewed regularly and can be accessed through the NCEC website at: www.health.gov.ie/patient-safety/ncec

Whilst there have been slight variations in the model adopted, most GDGs are composed of multidisciplinary key stakeholders, many of whom are working full time in clinical practice. They are supported, in the main, on a part-time basis by programme/project managers. Some, but not all, may have attended short NCEC training courses to gain the necessary knowledge for guideline development. Health service librarians assist with literature searching but there is no dedicated resource. In addition, support has been provided by the Health Information Quality Authority (HIQA) Health Technology Assessment division in terms of budget impact analysis on a goodwill basis. So the capacity to deliver robust clinical guidelines in a timely fashion, especially around the systematic review and evaluation of existing evidence has been limited. In response, the CEU issued standalone tenders in recent times to engage the services of appropriate teams in third level institutions to complete the required clinical effectiveness and/or economic systematic reviews to feed into guideline development. However, notwithstanding high quality outcomes, this approach resulted in (i) an increased burden on the research teams making single/multiple applications within tight timeframes (ii) a high administrative burden for the CEU and (iii) skill and expertise dispersal rather than the preferred establishment of critical mass, collaboration and scalability in synthesizing evidence for practice and policy. To that end, the CEU/NCEC have articulated a preference for establishing a more structured, efficient, and sustainable model for delivering clinical effectiveness, health economic and budget impact analysis inputs for future prioritised National Clinical Guidelines and their rapid (where compelling new evidence is available) or 3-yearly updates. Although not yet modelled, there is also an expectation that, if required, systematically reviewing the evidence base for establishing standards for future prioritised National Clinical Audit may be a requirement.

The HRB has a longstanding track record in supporting systematic reviews of evidence to underpin healthcare decision making. Through HRB funding, and in partnership with the HSC RDO in Northern Ireland, the island of Ireland became the first place in the world to provide free access for all citizens to the Cochrane Library. Almost 15 years later, a significant number of researchers, practitioners, educators, information scientists and others have participated in annually-delivered Cochrane training courses and workshops covering all aspects of systematic reviewing and meta-analysis. Furthermore, more than 130 individuals have been awarded Cochrane Fellowships to provide them with protected time and intensive training to complete

a systematic review and/or updates for incorporation into the Cochrane Library. The HRB through its wider investments in capacity building has also contributed greatly to the building of capacity in health economics, particularly at doctoral and post-doctoral level.

In recent years the HRB has worked with the NCEC to provide support for training in systematic reviews and through participation in working groups of the NCEC. In its recently launched Strategic Plan (2016-2020)[3] the HRB has as one of its stated objectives 'to promote and support evidence synthesis and knowledge translation activities in order to help policy makers, service planner and providers to make evidence-informed decisions'. A significant development in this regard is a strategic collaboration between HRB, NCEC and the CEU to develop a model to support the work of the NCEC in providing evidence for health care services in Ireland. All parties have agreed to support the establishment of an independent entity known as the **Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER)**. The aim of this national resource would be to conduct the systematic clinical effectiveness and economic literature reviews and the budget impact analysis for NCEC-prioritised guidelines and audit with a view to presenting the summarised evidence to the CEU and its nominated GDGs or committees.

Open call for proposals to develop the Collaboration in Ireland for Clinical Effectiveness Reviews (CICER)

Scope

The HRB invites proposals for the development and management of HRB-CICER. The award for HRB-CICER is for five years. An interim review will be carried out at approximately 30 months and subsequent funding will be dependent on a successful review. As the peer review and selection process will not be completed until Q3 2016, the scope of this call relates solely to the work required by the NCEC over the time period 2017–2021. Importantly, however, while HRB-CICER activity relating to systematic reviews will not begin until 2017, it is expected that the Director of HRB-CICER will be in a position to engage with NCEC/CEU in late 2016 to discuss detailed business planning for 2017. Applicants may apply for funding up to a maximum of €2.25 million over five years (inclusive of overheads).

It is anticipated that HRB-CICER would consist of an interdisciplinary team of researchers comprising research specialists in systemic reviewing, health economics and information sciences. Given the need to undertake different levels of work at different time periods and the need to have scope and flexibility to scale-up or scale-down activities as needed, it is anticipated that HRB-CICER 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).

In addition, HRB-CICER should have clear and explicit leadership and the nominated Director of HRB-CICER should have experience and expertise working in the area of evidence synthesis and also have experience of working with national bodies such as the Department of Health and/or Health Service Executive to deliver nationally relevant research projects to budget and under tight time-frames.

Objectives and Deliverables

The objective of this open competitive call is to make one award for the Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER) to support the work of the NCEC/CEU with regard to the evidence requirements for the clinical effectiveness processes across all areas as laid out in the NCEC Terms of Reference. HRB-CICER will undertake evidence reviews and provide scientific support for the development of the NCEC's clinical practice guidelines and other activities relating to the work of the NCEC.

It is expected that the **objectives** of HRB-CICER will include:

[3] http://www.hrb.ie/publications/hrb-publication/publications//702/

1. The conduct, in line with NCEC methodology and requirements, of systematic clinical effectiveness, economic literature reviews and budget impact analysis for NCEC-prioritised guidelines and audit and presentation of the summarised evidence to the CEU and its nominated guideline development groups or committees;
2. Provision of advice to the NCEC in relation to developments and advancements in evidence synthesis methodology through the participation of the Director of CICER in the NCEC meetings;
3. Development and delivery of advanced education and training sessions to relevant individuals as required, including guideline development groups, audit standard setting groups and other relevant individuals;
4. Participation in scoping, planning and agreement of review protocols;
5. Production of robust systematic reviews and analysis based on review protocols;
6. Engagement with development groups to formulate recommendations or standards based on reviews;
7. Maintenance of a register of research gaps emanating from guideline development

Governance and practical arrangements

The NCEC will act as the Steering Committee for HRB-CICER. The Director of HRB-CICER will be expected to attend NCEC meetings and report to the NCEC Committee at least twice-yearly on CICER activities. Representatives from the CEU and the Director of HRB-CICER will form an Executive Committee who will be responsible for planning a yearly calendar of HRB-CICER activities based on the CEU's Business Plan. Business planning will begin in Quarter 4 of each year for the forthcoming year. The Executive Committee will meet on a quarterly basis to ensure responsiveness of the calendar (e.g. mapping progress, flagging risks or prioritising activity). Annual deliverables will be set at the Executive Committee business planning meeting along with timelines for the deliverables. The timeframe for each deliverable will depend on the scope and nature of the review and will also be determined by the outcome of the prioritisation process that is undertaken at the annual Executive Committee business planning meeting.

In the first year of operation, HRB-CICER will be expected to produce 3-4 reviews and 5 review updates on topics identified by the NCEC. In subsequent years HRB-CICER will be expected to complete 4–6 reviews and approximately 5 review updates as required. It is acknowledged by all that these reviews will be of varying scope and size, and therefore duration, depending on the topic under consideration. Timelines for individual topics may also be staggered. While HRB-CICER 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. HRB-CICER 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' HRB-CICER research team.

The HRB-CICER researcher(s) will be based at their own location. A member of the guideline development group (GDG) and DoH's CEU will be assigned as the literature review contact for each guideline topic and this review-specific steering group will be the main point of contact for the HRB-CICER researcher(s). There will be at least four meetings between HRB-CICER researcher(s) and this group. For the purposes of assisting with planning the application, a typical meeting and work schedule is provided in the table below:

Table 1: Typical meeting and work schedule for a broad topic

Week	Meeting
0	An introductory meeting to take place before the review starts to agree PICOs *(Population, Intervention, Comparison, and Outcomes of interest)*
4	A mid-point meeting where the HRB-CICER researcher(s) provide an update on the progress of the review
8	Submission of the draft final report and a meeting to discuss same
11	A wrap-up meeting for final comments by the group on the draft
12	Final report expected one week after wrap-up meeting
Hiatus while Guideline Development Group reviews evidence and prepares recommendations	
After agreement of evidence statements and recommendations (time allowance of 2 weeks)	Format of the final draft full version guideline in accordance with the NCEC template

The HRB-CICER researcher(s) will be required to submit the full review ahead of meeting week 8 to discuss the draft final report. After the meeting to discuss the draft report it is expected that the HRB-CICER review team will commit to make any reasonable changes deemed necessary within two weeks. A final meeting will then be held, which will formally conclude the review. Meetings may be held by telephone conference.

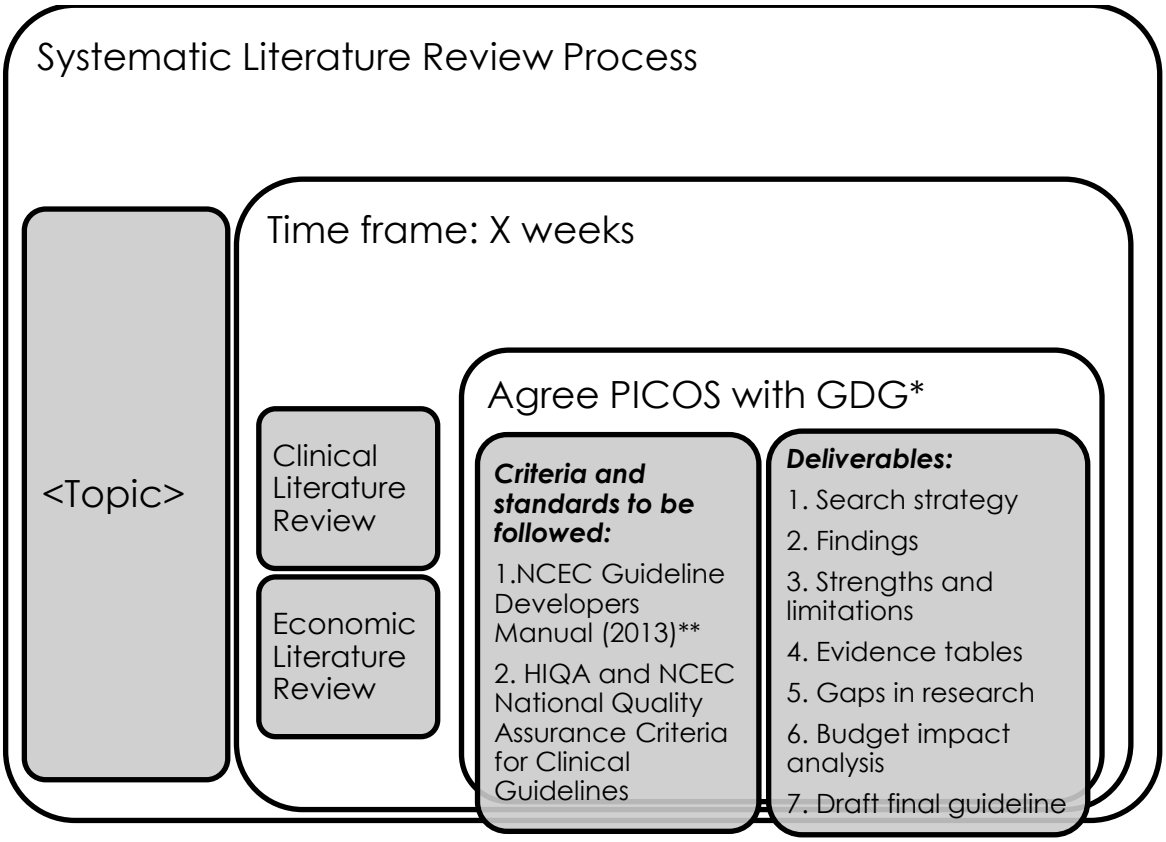
Figure 2 present a schematic representation of main considerations for HRB-CICER. Reviews should be carried out using a robust methodology. The NCEC Guideline Development Manual[4] outlines the steps necessary to carry out a systematic, qualilty assured literature review to support clinical guideline development and should be used as a reference guide when completing literature reviews. The manual is currently undergoing review and update but it is anticipated that all reviews should be conducted in line with the NCEC Guideline Development Manual version in use at the time of the review. The budget impact analysis should be conducted in line with HIQA's *Guidance on Budget Impact Analysis of Health Technologies in Ireland*.

The scope of literature searches should encompass international research and a full audit trail for articles with bibliographical detail should be included. In the first instance a search for relevant clinical guidelines should be carried out and where found, their quality should be appraised using the "rigour of development" domain as described by the *National Quality Assurance Criteria for Clinical Guidelines Version 2* (HIQA and NCEC, 2015). HRB-CICER researcher(s) should undertake a literature search for evidence of clinical and cost effectiveness, cost and resource impact, including primary (research studies) and secondary (reviews and economic evaluations) sources. Search strategies must be specified and should include relevant resources, such as trial/guideline registries and relevant citation databases (e.g. Medline, EMBASE, Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database, Health Technology Assessment

[4] Link to NCEC Guideline Development Manual, HIQA's Guidance on Budget Impact Assessment and other useful resources http://health.gov.ie/patient-safety/ncec/resources-and-learning/ncec-processes-and-templates/

Database and Cochrane Database of Systematic Reviews). The parameters, (i.e., population, interventions, comparisons, and outcomes (PICOs)) should be presented along with the review methodology, including the search strategy, detailed search terms and methods for quality appraisal and evidence synthesis that were used. HRB-CICER researcher(s) may need to give consideration to a grey literature retrieval mechanism for specific topics. A clear description of this process and subsequent review of the grey literature should be included.

Figure 2: Schematic representation of main considerations for HRB-CICER



**PICOS for the economic systematic literature review will be agreed with HIQA*
**PICOS for the clinical systematic literature review will be agreed with the GDG*
***http://health.gov.ie/patient-safety/ncec/resources-and-learning/ncec-processes-and-templates*

The systematic clinical literature and economic literature review report should include:

- Summary of literature review;
- Description of search strategy (including PICOs);
- Characteristics of relevant studies and their findings and conclusions;
- Summary of the evidence of clinical effectiveness of the guideline topic (the level of research evidence for each study should be identified and in addition, an evidence table presented);
- Strengths and limitations of the reviewed literature;
- Any knowledge gaps in the research;
- Characteristics of relevant economic evaluations and their findings and conclusions;
- Summary of the evidence of resource impact, cost impact and cost effectiveness;
- A budget impact analysis of implementation of the guideline (as per HIQA's *Guidance on Budget Impact Analysis of Health Technologies in Ireland* (July 2015));
- List of references.

All information required for inclusion in the full version final guideline must be presented in the NCEC template. The template for this is available on the NCEC website at www.health.gov.ie/patient-safety/ncec. Examples of systematic literature reviews and budget impact analysis for NCEC guidelines are available on the NCEC website at http://health.gov.ie/patient-safety/ncec/national-clinical-guidelines-2/.

Copyright and Publication

Copyright will lie with the Department of Health and all primary deliverables will be published as part of the National Clinical Guideline or equivalent. The knowledge translation of primary deliverables from CICER is the responsibility of the NCEC. However, the NCEC/CEU/Department of Health acknowledges the work of any material developed by CICER. Consultation must occur with the CEU/NCEC in advance of any proposed publication or presentation of papers, studies, promotional materials or similar materials related to work completed for the purposes of this call. The CEU/NCEC will have twenty working days to review and comment on the proposed publication, during which they may, acting reasonably:

- Specify changes; and/or
- Require the removal of any confidential information and/or proprietary information owned by the Department; and/or
- Request the removal of any material which, in the opinion of the Department, is of a sensitive nature
- Request a delay to publication.

The NCEC/CEU must be acknowledged in all subsequent papers or publications based upon or incorporating research conducted as part of this award.

It should be noted that the NCEC is currently developing a framework for publication emanating from its work, which will be available in 2016. CICER will be expected to comply with this framework, once published.

Management and reporting for successful award

The HRB will have responsibility for managing the award including contracting, payments, progress reporting (technical and financial) and evaluation. This will be in addition to the requirement of HRB-CICER to attend NCEC meetings at least twice-yearly and engaging as members of the Executive Committee for the purposes of annual business planning.

Eligibility criteria

Host Institution

While it is anticipated that applications may be multi-institutional, one institution must be appointed as the designated Host Institution (HI) for the purposes of managing the HRB award. A *HRB Host Institution* will be a research-performing organisation in the Republic of Ireland that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all HRB terms and conditions of awards. This is typically that of the lead applicant but may be another organisation /institution where this is properly justified. A list of currently approved HRB Host Institutions can be found at: http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/.

HRB-CICER Team Composition

Lead Applicant

While encouraging a diversity of disciplines on the HRB-CICER applicant team, one member should be designated as the lead applicant and for the purpose of this HRB award, the lead applicant should be the individual who will take up the position of Director of HRB-CICER. It is expected that this critical appointment will not be for less than 0.5 FTE and funding for same can be requested from the award. It is expected that the Director of HRB-CICER will have a strong track record and experience in systematic reviews and in

delivering high-quality, timely and relevant evidence for non-academic organisations such as the Department of Health, the Health Service Executive or a related organisation/s. In addition, the Director must also demonstrate a high level of competency and a demonstrable track record in leadership and strategic thinking, delivering results, building and maintaining relationships and effective communication. This is critical if HRB-CICER is to deliver to the necessary standards and timelines, to have a credible presence nationally and internationally in the field of evidence synthesis for clinical guidelines and to secure additional funding linked to other emerging opportunities.

The Director will be the primary point of contact for the HRB and the NCEC. They will be responsible for the scientific and technical direction of HRB-CICER and will have primary responsibility and accountability for carrying out the activities of HRB-CICER within the funding limits awarded and in accordance with the terms and conditions of the HRB award. The Lead Applicant must hold a permanent post in a recognised research organisation in the Republic of Ireland as an independent investigator.

Co-applicants and Collaborators

HRB-CICER applicant team members should possess the necessary expertise and experience in systemic reviewing, health economics, information sciences, project management and otherwise to ensure delivery of all of the objectives set out for HRB-CICER. In addition to the Director, up to eight Co-Applicants and eight Collaborators can be included. Individuals and/or organisations outside of the Republic of Ireland can be included where appropriately justified. Co-applicants should have a well-defined, critical and substantial role in the conduct and steering of the proposed HRB-CICER activities and must provide detailed summary of their experience and prior expertise. For each collaborator, a **Collaboration Agreement Form** should be completed setting out in detail the nature and scope of the collaboration, describing how the Collaborator will be involved in the proposed activities and the value they will add and details of the costs requested, where relevant, and appropriate justifications.

HRB-CICER research team

The application should include detailed information on the proposed 'core' HRB-CICER team but should also provide details of mechanisms to be employed in order to access specific and/or additional expertise, when required. Where the applicant team proposes to engage researchers/others as part of the HRB-CICER team, and where these individuals are known, their details including a CV should be included. Where posts or roles are indicated, but where individuals have not yet been identified, detailed role specifications should be included.

Individually and collectively, the HRB-CICER applicant team (and their affiliated institutions) must show that they have:

- The necessary knowledge, expertise and experience to oversee the conduct of high quality systematic reviews, meta-analyses and health economic evaluations and budget impact analyses;
- Complementary expertise among team members and access to additional topic-specific expertise, as required;
- Experience working in interdisciplinary and multidisciplinary initiatives including those with various parties and stakeholders;
- Worked successfully with Government agencies or other knowledge users in the production and/or use of evidence synthesis in healthcare settings;
- A proven track record of productivity and delivering results to tight deadlines;
- Experience in providing training and support linked to the objectives of HRB-CICER;
- Access to infrastructure from their affiliated institutions and collaborators to support the work of the HRB-CICER
- The right blend of technical and operational management experience to ensure that HRB-CICER delivers on time and to the necessary quality and standards.

Funding available

The total funding available will be €2.25 million over five years. Allowable costs include:

- Salary and salary-related costs
- Running costs (including small items of equipment)
- Administrative costs
- Training Costs
- Education and Outreach costs
- Dissemination Costs
- Overhead costs (at 25%)

Application and review process

The HRB is committed to an open and transparent international peer review process. While the process will be run and managed by the HRB, there will be input from the strategic partners (NCEC/CEU and representatives of HIQA HTA division). A grant selection panel comprising international experts in a range of relevant research areas and from a range of disciplines will be established to meet face-to-face to consider applications.

Comments from the grant selection panel will be available to all applicants on their GEMS homepage and they will have a time-limited opportunity (10 working days) to respond to the panel comments. This is an extremely important opportunity for the applicant teams to address any factual errors, conceptual misunderstandings or differences of opinion that can be perceived as weakness or concerns and provides an opportunity to take on board any constructive feedback that will improve the application. The applicant team responses will be available to the grant selection panel prior to the grant selection meeting discussions. Short-listing may be necessary at this stage.

Selected applicant teams will meet with the panel to present an overview of their proposal and to answer any queries or comments the panel may have prior to making a decision. The panel will make their final recommendation to the Board of the HRB prior to September 2016.

The panel will review applications based on the two main assessment criteria below. The assessment criteria will be equally weighted and successful applicants are expected to perform highly on both criteria.

Expertise and experience of the applicant team:

- Knowledge, expertise and experience of the applicants;
- Past experience and contributions to evidence synthesis including search strategies, critical appraisal, systematic reviews, meta-analysis, economic evaluations and budget impact analysis;
- Complementary expertise and access to additional topic specific expertise;
- Experience in working in interdisciplinary and multi-institutional initiatives including evidence of working with public bodies to deliver results in tight deadlines;
- The extent to which the applicant team has demonstrated evidence of plans to collaborate with key organisations/groups/teams to deliver scale, specialism, responsiveness and value for money;
- Experience of working with key groups associated with delivering for Clinical Guidelines (e.g. Clinical Guideline Appraisal Groups, Guideline Development Groups).

Merit of the application:

- A good understanding of the brief setting out the objectives of HRB-CICER and an appropriate plan to address these requirements;
- The extent to which the application shows originality and innovation;
- The extent to which the vision, aims and objectives are clear;

- The extent to which the structure is appropriate including governance, strategic oversight and administrative oversight;
- Institutional support and access to infrastructure;
- How the applicants propose to address all of the requirements of the NCEC, to conduct topic reviews concurrently and to be adaptive;
- The applicants approach to project management in terms of methodology, timeframes, deliverables, resources, control mechanisms and risk management

Key timelines

Board Approval to issue call	Feb 2016
Call open	15 March 2016
Call closed	1 June 2016
Review Period	July 2016
Right to respond	July 2016
International Panel Meeting	August 2016
HRB Board Approval	September 2016
Issue Contract	October 2016

Contacts

For further information on the HRB-CICER Award 2016 contact:

Sara Lord
Project Officer
Health Research Board
slord@hrb.ie

Appendix I: Detailed Guidance on the Application Form

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

Please refer to the GEMS Technical Guidance Note for further information.

The **Lead Applicant** must create the application but it can then be jointly completed with the 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.

Once the Lead Applicant selects the HRB-CICER scheme on GEMS, s/he will be asked to go through a check list of mandatory Yes/No questions. In order to start the application the Lead Applicant must satisfy the conditions of this check list.

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 and Signatory Notification

Host Institution

While it is anticipated that applications may be multi-institutional, one institution must be appointed as the designated Host Institution (HI) for the purposes of managing the HRB award. A *HRB Host Institution* will be a research-performing organisation in the Republic of Ireland that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all HRB terms and conditions of awards. This is typically that of the lead applicant but may be another organisation /institution where this is properly justified.

A list of the Host Institutions approved by the HRB at the time of this call going live is included as a PDF on GEMS. 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 HI, you will be assisted with auto-select options. It is important that the HI name is entered accurately and in full as an incorrect entry may result in delays in attaining HI approvals.

A list of currently approved HRB Host Institutions can also be found at:
http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/.

Signatory Notification (within Host Institution)

Once the Host Institution is selected at the initial stages of application creation this will allow the Principal Investigator 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 CICER 2016. 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 HI 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 HI signatory must confirm their willingness to participate as HI 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.

Lead Applicant, Co-Applicants and Collaborators contact details

Lead Applicant's Details

Details are requested about the Lead Applicant including their position and status and whether they are seeking salary-related costs and their supervisory experience. The Lead Applicant must hold a permanent post in a recognised research organisation in the Republic of Ireland as an independent investigator.

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

Publications and Funding Record

You are asked to add your 10 most **relevant publications** to this application on which you have acted as senior author.

You should also include your 5 most **relevant funding** awards as Principal Investigator or co-applicant.

For the purpose of this application form Publications and 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.

Evidence of Relevant Expertise

Lead Applicants are also asked to provide any evidence of expertise they may have in previous or current roles in conducting systematic reviews and in delivering high-quality, timely and relevant evidence for non-academic organisations (such as the Department of Health, the Health Service Executive or a related organization/s). The word limit is **500 words**.

The Lead Applicant will take the position of the Director of CICER and will be the primary point of contact for the HRB and the NCEC. It is expected that they will have a strong track record and experience in systematic reviews and in delivering high-quality, timely and relevant evidence for non-academic organisations such as the Department of Health, the Health Service Executive or a related organisation. Relevant experience may include:

- Past experience and contributions, including leadership, to conducting evidence synthesis including systematic reviews and meta-analysis of health research;
- Experience in economic literature reviews and budget impact analysis
- Complimentary expertise and access to additional topic specific expertise when required and to include methodological advancements in the area of evidence synthesis and its use.

Evidence of relevant leadership experience

Lead Applicants are asked to provide evidence of a high level of competency and evidence of track a record in leadership and strategic thinking, delivering results, building and maintaining relationships and effective communication. These skills are critical if HRB-CICER is to deliver to the necessary standards and timelines, to have credible presence nationally and internationally in the field of evidence synthesis for clinical guidelines and to secure additional funding linked to other emerging opportunities. The word limit is **500 words.**

Achievements outlined should be relevant to this application. They may include:

- Evidence of similar leadership/directorship roles, including those that had co-applicants and collaborators
- Experience in working in interdisciplinary, multi-disciplinary and multi-institutional initiatives including evidence of working with public and policy bodies to deliver results in tight deadlines
- Being able to demonstrate other outputs appropriate to delivering and communicating research findings to non-academic audiences to influence decision making in policy and practice
- Evidence of participating in senior decision fora

Supervision and mentoring of more junior researchers

Lead Applicants are asked to provide any relevant information in relation to experience in team building, mentoring of individual's research careers, or training for more junior researchers. Particularly mention experience in providing supervision and mentoring of more junior researchers undertaking evidence synthesis or related activities. The word limit is **300 words**.

Co-Applicants

The Lead Applicant can add up to 8 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 consent to the application being submitted jointly in their name. If a co-applicant rejects participation on an application the PI is informed and may revise the application accordingly. Co-applicants which accept to participate in an application will be able to edit the application. The system will flag through a pop-up warning if another user is working on the application form at the same time. A member of the applicant team may choose to over-ride this pop-up message and continue to enter data but it advisable that they contact the other person directly to avoid losing data when applying the override function.

Prior to validation and submitting the application to the authorised signatory of the nominated Host Institution for the final approval stage, Co-applicants must also approve the content of the application.

Co-Applicants Contact and CV Details

Each co-applicant can manage their **contact and CV details** (Name, contact information, institution, present position, employment history, profession and membership details of professional bodies) 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 provide information including their 10 most **relevant publications** and their **relevant funding record.** Their current position and status (contract or permanent) will also be requested in the application form. Please note that a letter of support from the Host Institution must be provided if a Co-Applicant is on contract position and requesting his/her own salary for this project.

Host Institution **Letters of Support** must be provided for 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 recognized by the host institution upon receipt of the HRB CICER award as a contract researcher; (ii) has an independent office and research space/facilities for which he/she is fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise post-graduate students and post-doctorate researchers. Electronic signatures are acceptable for letters that are uploaded on the HRB GEMS system.

Evidence of Relevant Expertise and Experience

Co-Applicants will be asked to provide any evidence of expertise and experience they may have in their previous or current roles in conducting systematic reviews and in delivering high-quality, timely and relevant evidence for non-academic organisations (such as the Department of Health, the Health Service Executive or a related organization/s). They should also include their experience relevant to the role that they will undertake in the conduct and steering of the proposed HRB-CICER activities (if relevant).

The Co-Applicant will have a critical, well-defined and substantial role in the delivery of the proposed HRB-CICER activities. It is expected that they will have a track record and experience in the competencies relevant to the role they will undertake in HRB-CICER. This may include:

- Past experience and contributions to evidence synthesis including systematic reviews and meta-analysis of health research;
- Experience in economic literature reviews and budget impact analysis;
- Collaborating, delivering and/or communicating research findings to non-academic organisations;
- Supervision and mentoring of more junior researchers.

The word limit is **500 words**.

Collaborators Details

The Lead Applicant can add up to 8 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, 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 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.

Details of Research Team

Applicant Team Composition

The Lead Applicant will be asked to provide an overview of how they will ensure HRB-CICER would consist of an interdisciplinary team of researchers with the appropriate expertise and experience required and how they will work together to achieve the objectives of the HRB-CICER. It is expected the team will comprise of research specialists in systematic reviewing, health economics and information sciences. Information on personnel to be funded through this award is requested below.

The Lead Applicant should describe:

- The applicant team members experience and methodological and statistical expertise for evidence synthesis and meta-analysis including economic analysis and modelling
- The roles and responsibilities of the applicant team members
- The plan in place to include a librarian assistant
- How the expertise of the applicant will benefit the work of the NCEC/CEU
- Other skills/experience/expertise that may be required to meet the objectives of HRB-CICER that is not included as part of the applicant team and how you will garner these if required

The word limit is **1000 words**.

Personnel

Give full details of all personnel to be funded through this project. Give a detailed justification for the nature of the research personnel relative to the scale and complexity of the project. If funding is requested for known personnel, please include the following details: Name, address, present position, academic qualifications and professional qualifications. The word limit is **500 words**.

Proposal Details

Title

The Lead Applicant will be asked to insert the following title: **HRB Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER)**

Award Duration and Start date

Please indicate the expected start date. Please note that the earliest start date will be **November 2016**. The duration of the award will be 60 months.

NOTE: While the activities of the award relating to systematic reviews will not start until 2017 it is expected that the Director will be in a position to engage with NCEC/CEU in late 2016 to discuss business planning for 2017.

Lay Summary

You are asked to provide a brief summary of the proposed activities including how you plan to address the requirements of the NCEC/CEU as a collaboration.

The lay summary needs to be written as a plain English summary, such that it is a stand-alone document that is clear, easy to understand, and is easily accessible to a broad lay audience. Avoid the use of highly technical terms. This summary may be used when providing information to the public concerning the variety of research funded by the HRB. The word limit is **300 words.**

Keywords

Please enter up to 5 keywords that specifically describes your activities.

Proposal Description

Overall Aim

Please state the overall aim of HRB-CICER. The word limit is **100 words.**

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.

Objectives should be relevant to the NCEC/CEU mandate and fit with its needs and requirements. **Please read the Guidance Notes carefully before completing this section**

Work plan for HRB-CICER

You are asked to provide a clear and concise description of the work plan for the proposed HRB-CICER. You should describe how these funds will be used to accomplish the goals and objectives set out for the collaborative. You will also be expected to summarize your understanding of the objectives of the HRB-CICER, the NCEC and the Guideline Development Groups and reflect your understanding of the required procedure as laid out in the NCEC Guideline Development Manual.
Proposals should outline specific technical resources and supports available and should detail their approach to project management in terms of methodology, timeframes, deliverables, resources, control mechanisms and risk management. The plan should be in line with the objectives, deliverables and milestones you have provided.

Your proposed plan should include, inter alia, the following information:

- Technical approach to the topics identified consistent with the NCEC Guideline Development Manual
- The feasibility of the approach ensuring that the HRB-CICER will be able to deliver
- Show an understanding of the NCEC/CEU objectives and requirements and any procedures/processes and how they will impact on how the collaborative will work
- Proposed plans for acquiring additional expertise/experience when required if not part of the applicant team
- Dissemination and knowledge exchange plan on how the activities will be communicated and reported consistent with the NCEC/CEU approach as well as other strategies that will be used to communicate the work of the HRB-CICER more broadly

Note: The word limit is set high at 5000 words maximum to facilitate the space required to describe the range of activities that will be undertaken by HRB-CICER. However you are advised to use common sense and good judgment when writing this section, which should be clear, succinct, yet thorough description of the plans for the development and management of HRB-CICER.

A file upload option is available to include an attachment to support your Proposal Work plan. This may be uploaded as a single document on HRB GEMS. This must not be embedded within the text of the Proposal Description. The maximum size is 2MB.

Governance & Management

You are asked to describe what arrangements will be in place for the management of the core infrastructure aligned with the information on Guidance Notes.

You should describe any oversight, advisory or governance structures that are crucial to delivery of the HRB-CICER objectives. You should also outline the processes that will be put in place to ensure that the collaborative is well managed from an administrative perspective, including project management processes, meetings schedules, financial management etc.

Describe:

- Plan for the core infrastructure for the collaborative including how it will be managed, the physical space available etc.
- Relevant affiliations of the collaborative who may participate in the completion of systematic reviews
- Provide a summary of key risks and plans to mitigate these risks

The word limit is **300 words**.

Monitoring and Evaluation

You are asked to describe what arrangements you propose to put in place to oversee and monitor the collaborative internally. This should include information on potential indicators and the ability to monitor and report on them and the overall approach to evaluating the work of the proposed HRB-CICER.

The word limit is **400 words**.

Award Budget

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

The total funding available will be €2.25 million over five years.

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.

Funds will be provided for the following:

1. **Personnel costs**	Must be listed for each salaried personnel under each of the following subheadings (a-e):
a) Salary	Gross Annual Salary (including 5% employee pension contribution) negotiated and agreed with host institution. Applicants should use the IUA website scales for the most up-to-date recommended salary scales for academic researchers **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. Please state the pay scale used and the level and point on the scale. This should be justified accordingly. For appointment of Research Fellows or Senior Research Fellows evidence of position must be provided at point of award. No annual salary increases will be paid. **Note:** The HRB does not provide funding for the salary or benefits of academic staff within research institutions who 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 10.75% of gross salary.
c) Employer Pension Contribution	Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution. 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 activities of HRB-CICER relating to the work of the NCEC/CEU including materials and consumables, travel for meetings, etc. Access to necessary special facilities or services which are not available in the applicant institutions. i.e., consultancy fees, methodological support, etc. will be considered under running costs as long as they are appropriately justified. <u>Note: Please see a list of costs that fall within the overhead contribution below and should not be listed here.</u>

3. **Equipment**	Funding for small items of equipment can be included in this section. Stand alone computers will not be funded. All costs must be inclusive of VAT, where applicable.
4. **Training Costs**	This includes training courses or workshops for personnel funded through the award. It does not cover training that will be provided by HRB-CICER. This should be included in the running costs.
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 outcomes as detailed in the dissemination and knowledge exchange plan.
6. **Administrative Costs**	This will include costs associated with the administration of HRB-CICER outside of salary costs and running costs. It may include advertisement and recruitment provided that it is fully justified.
7. **Education and Outreach Costs**	This includes activities relating to any outreach activities to promote awareness and understanding of the work of HRB-CICER.
8. **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 Costs for desk based research. 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.

Submission of Applications

The deadline for submission of complete applications is 1st June 2016 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.

Appendix II: Host Institutions approved by the HRB

The following research performing organisations are approved HRB Host Institutions

- Dublin City University
- Dublin Institute of Technology
- Economic and Social Research Institute
- National Cancer Registry Ireland
- National University of Ireland, Galway
- National University of Ireland, Maynooth (Maynooth University)
- Royal College of Surgeons in Ireland
- The University of Dublin (Trinity College Dublin)
- University College Cork
- University College Dublin
- University of Limerick
- Waterford Institute of Technology

The HRB host institution list is updated as new host institutions are approved. Please refer to our website page on host institutions for the most up to date list.

http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/