Health Research Awards (HRA) 2014

Guidance Notes

Key Dates & Times	
Application Opening date	**11 September, 2013**
Application Closing Date *	**30 October 2013, 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 Principal Investigators 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.*

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1. Introduction

The Health Research Board (HRB) *Strategic Business Plan 2010-2014 – The Future of Irish Health Research*, sets out the lead role of the HRB in Ireland in bridging the gap between generation of new knowledge in health and social care and the effective translation of that knowledge into benefits for health policy and practice.

In line with its strategic objectives, the HRB is now inviting applications for its 2014 Health Research Awards (HRA).

1.1 Objective

The Health Research Awards aims to fund researchers and research teams to conduct internationally competitive and innovative research that will create new knowledge and evidence of benefit to health through investment in patient-oriented research, population health and health services research.

1.2 Summary of key changes from previous HRA calls

Suggested improvements and refinements of the HRA scheme have been recently approved by the HRB Board following internal reflection on the scheme and taking on board comments from international panel members.

1.2.1 Timeframe for this and future HRA calls

The HRA call will no longer be announced on an annual basis. The timeframe for the next three HRA calls are proposed as follows:

- HRA 2014 – call announced during September 2013 with HRB Board approval by June 2014 for projects commencing from September/October 2014 onwards;
- HRA 2016 – call announced during November 2014 with HRB Board approval by November 2015 for projects commencing from early 2016 onwards;
- HRA 2017 – call announced during July/August 2016 with HRB Board approval by June 2017 for projects commencing from September/October 2017 onwards.

1.2.2 Eligibility of Principal Investigators

The following revised eligibility will apply to all Principal Investigators. A Principal Investigator must:

- Demonstrate research independence through securing at least one peer-reviewed research grant as the lead applicant from a recognised national and/or international funding agency/council;
- Have secured 3 or more peer-reviewed publications as a senior author (first, last or corresponding or in those fields where alphabetic order authorship is the norm, joint author). Only original research publications, and not review articles, are acceptable;
- Display the capability and authority to mentor, manage and supervise post-graduate students, post-doctorate researchers, other personnel, relationships with Co-Applicants and Collaborators.

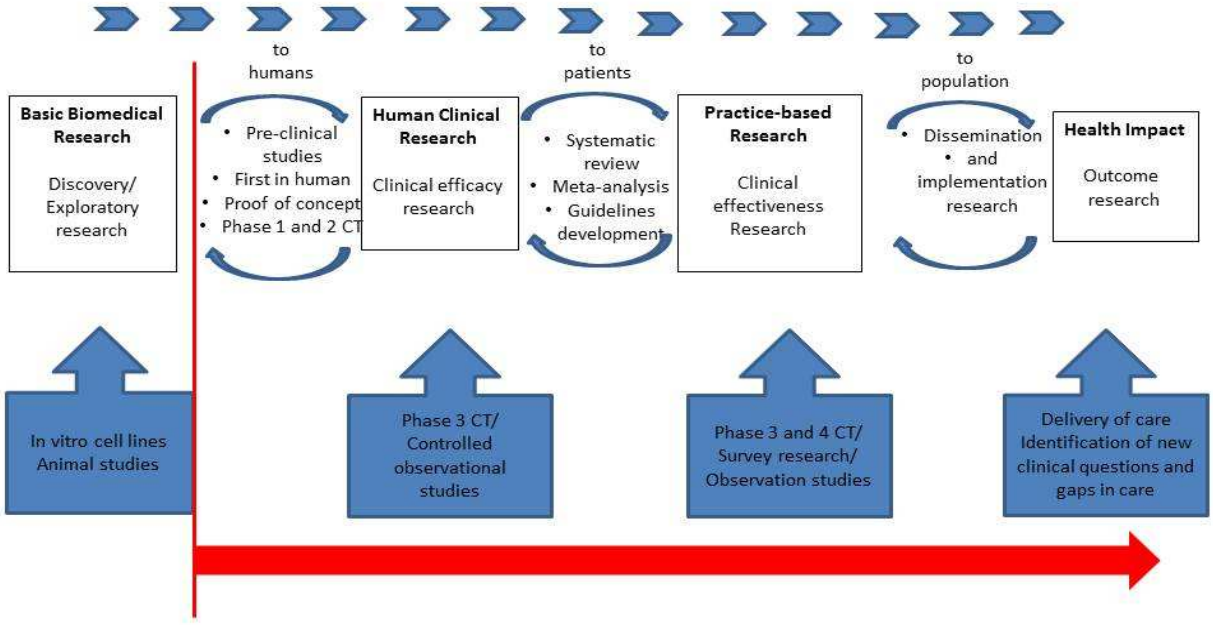
1.2.3 Remit of the Patient-Oriented Research (PoR) panel

The remit of the PoR panel is as follows:

Patient-oriented research is defined as research conducted with human subjects, or on material of human origin, such as tissues, specimens and cognitive phenomena. The research generally involves patients, samples and/or data from patient and other people who are not patients (e.g. healthy volunteers).

Only applications submitted to the PoR panel which focus on research activity to the right of the red line in diagram in the figure below will be considered within remit for this panel.

Figure 1: Continuum from research to impacts and outcomes



- The HRB will not support basic biomedical research or work involving cell lines, animals or their tissue. However, the HRB will consider research projects that involve work that constitutes 'pre-clinical' studies, on the understanding that pre-clinical studies represent an important stage of research that occurs before testing in humans to find out if a drug, treatment or procedure is likely to be useful. Such studies gather data on efficacy, feasibility, toxicity, safety and supports patient eligibility criteria. They typically involve research using particular species of animals and these are the only cases where the HRB will consider supporting animal work. However, to justify inclusion as a pre-clinical study appropriate evidence must be provided in the application setting out the rationale and the case for the pre-clinical study, justifying the choice of species in a manner which resembles the human condition in aetiology, pathophysiology, symptomatology and response to therapeutic intervention and describing how the pre-clinical study correlates and aligns with planned future stages of research in humans.

  In some pre-clinical studies where, due to the species-specific nature of the clinical product (e.g., some vector-expressed human transgenes or human derived cellular products) testing in animals would not prove informative or appropriate, alternative *in vitro* pre-clinical models may be proposed, but detailed justification must be provided.

- For research that involves biomarkers:
  - Research that aims to elucidate mechanisms underpinning disease or to identify risk factors for disease or prognosis (including searching for biomarkers) is out of remit.
  - Research that tests whether the application of new knowledge can improve treatment or patient outcomes, and has obvious potential benefit within five years, is within remit. This might include the validation of known biomarkers and/or other known risk factors which have an established relationship with a disease or clinical condition, or refining and testing novel therapeutic strategies.

1.2.4 Inclusion of an additional HRA sub-panel to provide support for larger-scale definitive intervention studies – Definitive Intervention Panel (HRA_DI)

In previous HRA rounds, applications to conduct RCTs/interventions studies and pilot/feasibility studies (in line with the MRC Guidance on the Evaluation of Complex Interventions) were always encouraged. The addition of this new panel aims to bring greater clarity for applicants applying for support for such studies. Numerous applicants have applied in previous rounds to design, develop and conduct an intervention study without any accompanying evidence around pilot, feasibility or acceptability studies. In every instance, grant panels have not recommended these applications for funding on the basis that there is not enough clarity or assurances about the nature, feasibility or cost of the final intervention or design. Hence, for the HRA 2014 round:

- If an applicant wishes to conduct an intervention study but has not previously conducted rigorous pilot and feasibility work, then they should apply for support to do so through whichever is the most appropriate of the PoR, PHS or HSR panels. These provide support for projects of up to €330,000 and for up to 36 months.
- Where an applicant has conducted prior pilot and feasibility work and is in a position to provide this evidence, then they may apply to the Definitive Intervention Panel for funding of up to €800,000 and for projects of up to 60 months in order to conduct the definitive intervention study. Specific guidance is provided to these applicants

and a specific application form is provided to capture the necessary information. Applicants can submit suitable applications to this panel regardless of whether it is patient-oriented, population health or health services research.

1.2.5 Collaborators

Collaborators named in the application form are now eligible to request funding from the award where this is properly described and justified.

1.2.6 Inclusion of a Rebuttal phase

For applications which are short-listed for discussion by a grant panel, the Principal Investigator will be provided with a time-limited opportunity to respond to the peer-reviewers' comments via GEMS. The PI response will then be brought to the attention of the panel for inclusion in the final review stage of the applications.

1.3 Scope of HRA 2014 call

The HRA (2014) invites applications to be submitted to one of four grant panels:

1. Patient-Oriented Research panel
2. Population Health Research panel
3. Health Services Research panel
4. Definitive Intervention panel

Applications submitted to the patient-oriented research panel, the population health research panel and the health services research panel should comprise clearly defined research projects (including pilot and feasibility studies) for up to **36 months** and a maximum award value of **€330,000** (inclusive of overheads).

Applications to the Definitive Intervention panel should comprise larger scale projects aimed at evaluating a definitive intervention (randomised clinical trials and/or other intervention studies involving humans) to provide high quality evidence on the efficacy, effectiveness and cost and broad impact of the intervention to patients, population health and/or the health services. These larger projects must fall under the remits defined for either PoR, HSR or PHR and must use an appropriate methodology (randomised or non-randomised design). The maximum value of awards supported through the DI panel is **€800,000** (inclusive of overheads) and proposed project durations must be appropriate to the scale of the intervention proposed, but cannot be beyond **60 months**. Applicants submitting projects to this panel must have previously conducted pilot, feasibility, and acceptability studies and should provide evidence of such as part of their application.

Further guidance and details on the research areas covered by the HRA panels can be found in Appendix II (page 42).

HRA (2014) will not fund:

- Applications which are solely literature reviews, audits, surveys, needs assessments or technology development (although these elements may be part of an integrated research study).
- Applications which are solely **or** predominately developing the infrastructure for biobanking, databases or patient registers without a predominant research element.
- Applications which are solely **or** predominately health service developments or implementation of an intervention without a predominant research element. The HRB will not fund the cost of providing the service or intervention itself, only the research element.
- Applications from individuals applying for, holding, or employed under a research grant from the tobacco industry.
- Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HRB cannot take on the role of sponsor so plans for appropriate sponsorship arrangements must be included in the application i.e. Letters of Support must be provided from sponsors or potential sponsors.

2. Eligibility Criteria of Principal Investigator, Co-Applicants and Collaborators

Applicants must demonstrate clearly that the research team contains the necessary breadth and depth of expertise in all the methodological areas required in the development and delivery of the proposed project. Appropriate multi- and inter-disciplinary involvement in the research team is essential and where relevant, experts in statistics, health economics, behavioural science, qualitative research, ICT, health informatics, etc. should be included as either Co-Applicants or Collaborators. For studies that require a lot of coordination, applicants should consider the appointment of a study manager or coordinator under Research Personnel.

With a core objective to support high quality research that is capable of translating into policy and/or practice, the HRB expects that applicants will collaborate, where appropriate, with partner organisations such as universities, hospitals, health agencies, local government and or voluntary organisations. Applicants should give significant consideration throughout the application process to stakeholders, partnerships, target audiences and appropriate knowledge exchange and dissemination strategies.

2.1 Principal Investigator

The Principal Investigator (PI) will serve as the primary point of contact for the HRB during the application and review process and for on-going management of the award, if successful. The PI will be responsible for the scientific and technical direction of the research programme and has 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 Principal Investigator must:

- Hold a post that covers the duration of the award in a recognised research institution in the Republic of Ireland (the "Host Institution") as an independent investigator, **or**
- be a contract researcher recognised by the Host institution as an independent investigator who will have a dedicated office and research space for the duration of award, for which he/she will be fully responsible, **or**
- be an individual who will be recognised by the Host Institution upon receipt of the HRB HRA award as a contract researcher as defined above. The Principal Investigator does not necessarily need to be employed by the Host Institution at the time of the application submission

In addition, the Principal Investigator must meet all of the following requirements:

- The Principal Investigator must demonstrate research independence through securing at least one peer-reviewed research grant as the lead applicant from a recognised national and/or international funding agency/council;
- Have secured 3 or more peer-reviewed publications as a senior author (first, last or corresponding or in those fields where alphabetic order authorship is the norm, joint author). Only original research publications, and not review articles, are acceptable;
- Have the capability and authority to mentor, manage and supervise post-graduate students, post-doctorate researchers, other personnel, relationships with Co-Applicants and Collaborators.

Only one application per Principal Investigator to this scheme will be considered.

2.2 Co-Applicants

A Co-Applicant has a well-defined, critical and substantial role in the proposed research. Co-Applicants from outside of the Republic of Ireland are welcome where appropriate and justified. A Co-Applicant may receive funding for items such as running costs and personnel but cannot receive support towards his/her own salary if they are in salaried positions. Co-Applicants can however request their own salary if they are contract independent investigators and depending on their role and percentage time dedicated to the research project **(up to a maximum of 5 Co-Applicants can be listed).**

Each Co-Applicant is invited to view the application form online and approve content prior to submission. The terms of any co-application should be determined early and relevant written agreements should be in place prior to the onset of the project. Consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when establishing co-application agreements.

2.3 Collaborators

An official Collaborator is an individual or an organisation who provides an integral and discrete contribution (direct or indirect) to the proposed research. A collaborator may supply samples or kits, may provide training in a technique, access to specific equipment, specialist staff time, trials advice or support, access to data and/or patients, instruments or protocols or may act in an

advisory capacity. They can be based in an academic institution, a private enterprise, a healthcare organisation or agency, or come from the charity sector. Collaborators may be based outside the Republic of Ireland where appropriate and justified. Collaborators are eligible to receive funding from the award when properly detailed and justified **(up to a maximum of 10 Collaborators can be listed).**

If the success of an application is dependent on access to healthy volunteers or patients, vulnerable population groups, data, databases or samples and/or if a study is part of another planned/existing national or international study (e.g. an existing cohort or longitudinal study), it is advised that you include these details and include the relevant gatekeepers as Collaborators within your application form. This will greatly assist the reviewers and panel members in reviewing aspects of commitment, access and overall project feasibility.

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 and this must be completed to include the following;

- Details setting out the nature of the collaboration and how the Collaborator will be involved in the proposed research and add value to the project;
- Confirmation of Collaborator's commitment to the proposed project;
- Details setting out the value, relevance and possible benefits of the proposed work to the Collaborator;
- Details setting out the period of input/support;
- Detail how the results of this collaboration will be disseminated;
- Details of the costs requested (where relevant) with appropriate justifications.

The terms of any collaboration should be determined early and relevant written agreements should be put in place prior to the onset of the project. Consideration should be given to issues such as responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up collaboration agreements.

2.4 Access to Clinical Research Infrastructures

Applicants availing of the input, advice, services and/or support of a Clinical Research Facility/Centre (CRF/CRC), a Clinical Trials Unit (CTU) or other specialist facilities (e.g. Centre for Advance Medical Imaging (CAMI), All Ireland Methodology Hub) during either the development and/or implementation phases of the project are required to provide additional information setting out the details of this engagement. An Infrastructure Agreement Form will be provided for this purpose as part of the application process.

Applications involving patients, which do not detail such input, advice and/or support (and where this expertise is not clearly evident within the applicant team) should justify why they have chosen not to access such support.

2.5 Host Institution

The Host Institution for the award is a recognised research institution in the Republic of Ireland. This is normally that of the Principal Investigator but it may be another organisation/institution designated by the research team, where it is clearly justified.

Host Institution Letters of Support must be provided for **(1) all Principal Investigators 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 recognized by the host institution upon receipt of the HRB HRA 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.

3. Funding

HRA awards provide funding up to a maximum award value of:

- **€330,000** (inclusive of overheads) for projects of up to 36 months submitted to the PoR, HSR and PHR panels;
- **€800,000** (inclusive of overheads) for larger-scale projects of up to 60 months submitted to the Definitive Interventions (DI) panel.

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

Note: The Health Research Awards do not fund the salary and related costs of tenured academic staff within research institutions (including buy out from teaching time etc.).

Note: As the primary aim of this scheme is to fund high quality, innovative research projects of international standing, applicants must demonstrate clearly that the level, expertise and experience of proposed research personnel matches the ambition and scale of the project and that they possess the necessary breadth and skills in all methodological areas required to deliver the proposed programme of work. Unlike the HRB's fellowships programmes, this scheme is not framed as a training initiative, and where junior personnel registered for a higher degree are proposed to work on projects, reviewers will thoroughly assess the level of baseline experience matched with the supervisory and up-skilling arrangements proposed in scoring the proposal.

4. Application Process

*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 (**30 October 2013, 13:00**).*

Prior to final submission to the HRB, all applications must first be reviewed and approved within GEMS by the Host Institution listed in the application form. It is critical therefore that Principal Investigators 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.

4.1 Overview of the application process:

- The Principal Investigator must be the one who creates the application, but once created it can be jointly completed by the Principal Investigator and named co-applicants.
- The PI must register on GEMs if they have not previously done so. They will receive an email confirming their registration and providing them with login details;
- Before starting the application, the applicants must **select one** of the four HRA panels based on which is the most appropriate to review the application:
    - Patient-Oriented Research panel
    - Population Health Research panel
    - Health Services Research panel
    - Definitive Intervention panel
- Once the PI selects the Panel, s/he will be asked to complete a checklist of mandatory 'Yes/No' questions. In order to begin the application process the PI must satisfy the conditions on this check list.
- Co-applicants can be added to an application by the PI. When a co-applicant is added, GEMS will automatically email them to invite their participation. Co-applicants can decide whether to accept or reject their inclusion, they can edit the application form and they can give their consent to the application being submitted.
- The PI and co-applicants can manage their contact details and their CVs in the 'My Details' section of GEMs. Once completed the CVs are automatically included in the application submission.
- When the application form is complete it must be validated by the PI to highlight any omissions in the form, and allow these omissions to be corrected.
- Once the application is validated by the PI and approved by the co-applicants the application is submitted for approval to the authorised signatory in the nominated Host Institution. Once the Host Institution is selected as part of the application, GEMS draws on the pre-populated contact details of authorised signatories within the Host Institution. Once the Host institution is selected in the application the relative signatory will be notified by email informing them that their approval is requested and providing them with access to a PDF version of the application form.
- The Principal Investigator may follow the progress of the HI approval process on the grant summary page in GEMs.

- If the HI signatory rejects the application, it will be sent with comments back to the Principal Investigator who can then address the comments and resubmit the application as before.
- When the HI signatory has approved the application, it will be sent automatically through GEMs to the HRB and a confirmation email will be sent to the Principal Investigator.

More detailed information on the application process can be found in the GEMS Technical Guidance Notes and in the Detailed Guidance on the Application Forms (Appendix IA and IB).

It is the responsibility of the Principal Investigator to select the most appropriate Panel to assess the application. Please read guidance on the remit of HRA Grant Selection Panels on Appendix II on page 42. If in doubt, they should contact the relevant HRA project officer in the HRB (see contacts on page 15 for further information). The HRB reserves the right to reassign an application to another Panel if that chosen by the Principal Investigator is deemed inappropriate. Where HRB staff members make a decision to transfer an application between Panels as part of the detailed eligibility check, the Principal Investigator will be informed. Similarly, where an applicant fails to meet the eligibility criteria or the application is deemed to be outside the scope of the scheme, the application will be deemed ineligible and the HRB will contact both the Principal Investigator and the Host Institution.

5. Application Review Process and Assessment Criteria

5.1 Review Process

The HRB is committed to an open and competitive application process underpinned by international peer review. The HRA scheme will use a two-phase assessment process which includes a rebuttal step for the PI.

- Phase One - Following an initial eligibility check by HRB staff applications are sent to international experts for analysis, comment and scoring. Each application is reviewed online by an average of three international peer reviewers. On the basis of the external peer review scores and comments, the proposals submitted to each Panel are ranked. Only the highest ranking proposals are brought forward to the second phase of peer review. In any instances where only one reviewer score is received and/or where significant inconsistencies exist between scoring, these applications are included for further discussion at the Panel meeting.
- Rebuttal Step: For applications short-listed for discussion at the Grant Panel meeting, the Principal Investigator will be provided with a time-limited opportunity to respond to the peer-reviewers' comments in order to address any factual errors or conceptual misunderstandings and/or to respond to queries or general comments highlighted by the reviewers. Once notified that the application is short-listed the peer-reviewers comments will be available to PIs on their GEMS personal page. Each PI will have **3 days only** to submit their response through GEMS, and the response has a maximum word count of **1200 words**. The PI's response will then be provided to members of the Panel in advance of their face-to-face meeting alongside the application and the peer-reviewers' comments. PIs are not obliged to submit a response but it is recommended that they do so as Panel members will consider these responses carefully as part of their final deliberations.

- Phase Two - Grant selection Panels comprising international experts in those areas will then be established to meet face-to-face to consider the short-listed applications, the comments of the peer reviewers and the PI responses with a view to making the final recommendations to the Board of the HRB. The exact number of applications funded per Panel will be determined by the quality of applications and available budget.

5.2 Confidentiality & Conflict of Interest Rules

- Throughout the process the identity of the peer reviewers are kept confidential and are not disclosed to the Principal Investigators. However, all of the international reviewers and Panel member's comments are issued to the Principal Investigator following the conclusion of the review process.
- Peer reviewers and Panel members are equally required to respect the confidentiality of the peer review process, which is designed to protect and preserve the integrity of the HRB's advisers and processes. Reviewers may not discuss any aspect of the scoring or assessment with applicants or colleagues. All such requests must be referred to the HRB.
- Conflict of interest rules are applied rigorously by the HRB. Where a conflict of interest exists, the reviewer is requested to inform the HRB immediately so that an alternative reviewer may be appointed. International peer reviewers will not be able to view the full application or provide comments or scores on any application on which they have a conflict of interest.

5.3 Assessment Criteria and Scoring of Applications

The assessment criteria used by the peer-reviewers and all panel members are as follows:

Scientific Quality and Innovation (60 marks)

- Clarity of the research question.
- The background to the proposed research, justifying the need for work in this area, drawing particularly on existing evidence.
- Completeness of the literature review and relevance to study design/research plan.
- Clarity of rationale for the research approach and methodology.
- Appropriateness of the research design.
- Appropriateness of the research methods.
- Feasibility of the research approach (including recruitment of subjects, project timeline, preliminary data where appropriate, etc.).
- Anticipation of difficulties that may be encountered in the research and plans for management.
- Originality of the proposed research in terms of hypotheses/research questions addressed, novel technology/methodology and or novel applications of current technology/methodology
- Potential for the creation of new or advancement of knowledge and evidence of benefit to the area covered by the research.
- The anticipated outputs, outcomes (e.g. patents) and impacts on practice and/or policy and decision making of the proposed research.
- The generalisability beyond the immediate research setting in a way that will maximise the impact of the results.

Expertise and Research Environment (40 marks)

- Qualifications of the applicant(s), including training, experience and independence (relative to career stage).
- Experience of the applicant(s) in the proposed area of research and with the proposed methodology.
- Expertise of the applicant(s), as demonstrated by scientific productivity over the past five years (publications, books, grants held, etc.). Productivity should be considered in the context of the norms for the research area, applicant experience and total research funding of the applicant.
- Track record of applicant(s) as demonstrated by the outputs, outcomes and impacts on the health of patients and/or the public arising from previous grants.
- Ability to successfully and appropriately disseminate research findings, as demonstrated by knowledge translation activities (publications, conference presentations, briefings, media engagements, etc.).
- Quality of the plan for using and disseminating the knowledge, potential for promoting innovation and clear plans for the management of intellectual property, where appropriate, to ensure optimal use of the project results for the patient and the healthcare system.
- Appropriateness of the team of applicants (if more than one applicant) to carry out the proposed research, in terms of complementarity of expertise and synergistic potential.
- Availability and accessibility of suitably qualified personnel, facilities and infrastructure required to conduct the research.
- Suitability of the environment to conduct the proposed research.

6. Timeframe

11 September 2013	Opening of call
30 October 2013, 13:00	Deadline for online submission of **all applications**
Late March/Early April 2014	Rebuttal phase (exact timing will vary between Panels)
May 2014	Panel Meetings will take place in May 2014 with a view to making final recommendations to the Board of the HRB in June 2014
June 2014	Following HRB Board approval of the recommendations, successful applicants will be notified of their success by late June 2014.

July/August 2014	Contracts will be issued in July 2013 with a view to beginning the research project from October 2014 onwards.

7. Contact

For further information on the Health Research Awards contact:
Sara Lord
Project Officer
Population Health and Health Services Research
Health Research Board
e **slord@hrb.ie**
t +353 1 2345 205

Please also refer to frequently asked questions on the HRB website.

The HRB reserves the right to reject any application that does not meet the terms of this call. The decision of the HRB Board in respect of any grant application is final and cannot be appealed or reviewed.

Appendix IA: Detailed Guidance on the Application Form for Patient-Oriented Research (PoR), Population Health Research (PHR) and Health Services Research (HSR) panels

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 Principal Investigator must create the application but it can then be jointly completed with named co-applicants.

- Principal Investigators can register on GEMS and they will receive an email to confirm their registration and log in details. The Principal Investigator can then add information on their contact and CV details in 'Manage My Details' section of GEMS.
- Principal Investigators 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. Applicants must select PoR, HSR, PHR or DI from among the four choices of HRA 2014 Panels, based on which is the most appropriate to review the application (please read the Remit of the HRB Grant Selection Panels in Appendix II page 42 of the Guidance Notes). This Appendix covers information for the PoR, PHR and HSR application forms. If you are submitting an application to the DI panel you should read the relevant guidance for completing that application form provided in Appendix IB (page 29):

- **Patient-Oriented Research**
- **Population Health Research**
- **Health Services Research**
- Definitive Intervention

Once the PI selects the Panel 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 PI must satisfy the conditions of this check list.

The Principal Investigator 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
The Host Institution for the HRB award is a recognised research institution in the Republic of Ireland. This is normally that of the Principal Investigator but it may be another organisation/institution designated by the research team, where it is clearly justified. A list of the Host Institutions recognised by the HRB at the time of this call going live is included in Appendix V and 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.

If you wish to propose a host institution which is not on the HRB list you are advised to contact the HRB at **gemshelp@hrb.ie.**

Signatory Notification (within Host Institution)
Once the Host Institution is selected at the initial stages of application creation this will allow the 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 Principal Investigator's intention to submit an application to the HRA 2014. 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 PI and if they have any queries or clarifications they can engage directly to resolve them with the PI. 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.

Principal Investigator, Co-Applicants and Collaborators contact details

Principal Investigator's Details
Details are requested about the Principal Investigator including their position and status (contract or permanent) and whether they are seeking salary-related costs and their supervisory experience. Please note that a letter of support from the Host Institution must be provided if the Principal Investigator is on contract position (see section 2.5 at page 10 for more details).

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

Co-Applicants
The Principal Investigator can add up to 5 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 PI 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 PI 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) **Publications and Funding Record (**List of all publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) where the applicant has acted as Principal Investigator or Co-Applicant) under 'Manage my Details' section of GEMS and this information will be automatically included in any application that involves this individual.
Please note that additional information regarding supervisory experience, if planning to supervise a student, and their current position and status (contract or permanent) will 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 (see section 2.5 at page 10 for more details)

Collaborators Details
The Principal Investigator 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 PI. The PI 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.

Project Details

Project Title
This should be descriptive and concise and should reflect the aim of the project.

Project Duration and Start date
Please indicate the expected length of the proposed project in months (maximum duration is 36 months). The anticipated start date should be realistic and would typically be between 3-6 months after HRB Board approval (June 2014).

Project Lay Summary
This lay summary is similar to the project abstract in that you are asked to describe what you propose to do, say why you think it is important to complete this piece of work and how you are going to go about conducting, analysing and drawing conclusions from the research. The difference is that it needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience. The lay summary may be used when providing information to the public with regards to the variety of research funded by the HRB and may be posted on the HRB website. The word limit is **300 words**.

Project Abstract
This should be a succinct summary of the proposed research. The aims and hypotheses of the project should be conveyed with clarity. The objectives of the project and what the work is expected to establish should be described. Ideally it provides a clear synopsis of your proposal and should set the research proposal in context. The word limit is **300 words**.

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

Project Description
You are advised to ensure that your application is focused and that sufficient evidence is provided to enable the international peer reviewers and grant selection panel members to reach a considered judgement as to the quality of your research proposal, its significance and its feasibility.

The Project Description must include:

- Current knowledge, background to the area of the proposed research and relevance (which should include a summary of any pilot work already undertaken, if relevant)
- Overall Aim
- Objectives and Deliverables (including Gantt chart or alternative)
- Research Design and Methodological approach
- Project Management
- Patients, User and Stakeholder Involvement
- Dissemination and Knowledge Exchange Plan

Current Knowledge, Background to the area and Relevance
Describe the background to the research proposal and detail the size and nature of the issue to be addressed. Include evidence from the literature and give references to any relevant systematic reviews. Where available, include a description of any pilot work, professional and consumer consensus studies already undertaken. Summarise the importance of the proposed research and describe the anticipated outputs, outcomes and impact of the proposed research, indicating the anticipated timescale for any proposed benefits to be realised. Provide a clear description of the problem to be addressed and explain why it is important and timely, especially in an Irish context.

Be aware that the peer reviewers reading your proposal will be based outside of Ireland, so it is important to describe the current healthcare delivery context in Ireland when discussing issues around need, relevance, timeliness and feasibility. Explain how the research has the potential to contribute to health and wellbeing in nationally and/or internationally. The word limit is **1200 words**.

Overall Aim
Please state the overall aim of the research project. 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 (e.g. PhD submission) and roles and responsibilities of the Principal Investigator team etc.

Research Design and Methodological Approach
Summarise the proposed research plan, providing descriptions of individual project/work streams or work packages and describe how they integrate to form a coherent research proposal. Include details of the general experimental approaches, study designs and techniques that will be used. Include details on all stages of the study design including rationale for sampling strategy, justification of sample size and power calculation, details on the design chosen and the intervention (where relevant), the methods of data collection, measures, instruments and techniques of analysis for quantitative and qualitative designs, outcomes measures and data analysis/management plans.

Notes:

- The HRB encourages the development and application of agreed standardised sets of outcomes, known as 'core outcome sets', such as those reported by the COMET (Core Outcome Measures in Effectiveness Trials) Initiative.
- If you are conducting a pilot or feasibility study you should review the MRC Guidelines on Evaluating Complex Interventions, the checklist provided for Intervention Studies in Appendix III and the CONSORT checklist highlighted in Appendix IV. Pilot studies represent a version of the main study that is run in miniature to test whether the components of the main study can work together. They resemble the main study in many respects including an assessment of the primary outcome. A well conducted pilot study should give a clear list of aims and objectives within a formal framework which will encourage methodological rigour, ensure that the work is scientific valid and publishable and will lead to high quality trials. They are focused on the processes of the main study to ensure recruitment, randomization, treatment and follow-up assessments all run smoothly.[1] Feasibility studies should be

[1]Gillian A. Lancaster et al. Design and analysis of pilot studies: recommendations for good practice. Journal of Evaluation in Clinical Practice, 10, 2, 307-312

conducted before a definitive study in order to answer the question "Can this study be done"? They are used to estimate important parameters that are needed to design the main study. In addition to describing the pilot/feasibility study, you should also provide a brief description of any information relevant to the planned intention to conduct a definitive study in the future, even if not part of this application.

- You are strongly advised to seek advice and input from an experienced research design and statistics expert in advance of submitting your application. Discrepancies and incorrect approaches in this section represent the most common source of feedback in unsuccessful HRB applications.
- Explain in detail how new techniques and/or or high-risk studies will be managed and suggest alternative approaches should these fail.
- Where new methods are being developed, arrangements for establishing validity and reliability should be described. Examples of non-standard questionnaires, tests, etc. should accompany the application or their content be clearly indicated.
- Useful links and resources are summarised in Appendix IV.

The word limit is **4500 words**

For applications that include a 'pre-clinical' study

For applications which contain one or more elements of a 'pre-clinical' study, applicants must provide additional information as follows:

- Provide appropriate evidence with regard to the relevance of the proposed animal species and model compared with humans (demonstration of relevance may include target expression distribution and primary structure; pharmacodynamics; metabolism and other pharmacokinetic aspects; and cross reactivity studies using human and animal tissues (e.g. monoclonal antibodies)) and
- Justify and document in detail the choice of species/model relative to the pathology and/or human condition (aetiology, pathophysiology, symptomatology and response to therapeutic intervention)[2] [3] and
- Describe how the proposed pre-clinical work correlates and aligns with any planned future stages of the research in humans even if not part of this application.

Note: In some pre-clinical studies where, due to the species-specific nature of the clinical product (e.g., some vector-expressed human transgenes or human derived cellular products) testing in animals would not prove informative or appropriate, alternative *in vitro* pre-clinical models may be proposed, but detailed justification must be provided.
Note: Where no relevant species exists, the use of homologous proteins or the use of relevant transgenic animals expressing the human target may be the only choice but in every instance a detailed justification of the pre-clinical model must be provided.

[2] US FDA (2009) Guidance for Industry, Animal models – Essential Elements to address efficacy under Animal Rule, 19pp. Silver Spring MD USA: US Department of Health and Human services, Food and Drug Administration.
[3] Committee for Medicinal products for Human Use (CHMP) (2007). Guidelines on Strategies to Identify and Mitigate Risks for First-in-human Clinical Trials with Investigational Medicinal products EMEA/CHMP/SWP/28367/07 12pp. London, UK: European Medicines Agency

The word limit is **1000 words**

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

Patients, User and Stakeholder Involvement
Please describe if patients and/or users and/or stakeholders have been actively involved in the preparation of this application and/or will be involved in the proposed research and if so provide details of the individuals/groups and the ways they are involved. If this is not applicable to your application please explain why. The word limit is **600 words**.

Note: The HRB encourages the involvement of consumers and patient advocate groups with the aim of better research and protocol design and greater usability of both the research project and its findings.

Dissemination and Knowledge Exchange Plan
Include a clear dissemination and knowledge exchange plan to indicate how information will be disseminated during and after your research. Who are the various audiences and communities that need to be targeted if these results are to have any impact? What is your dissemination plan to address this? Describe academic publication plans and/or plans for technology transfer. Describe how the findings of this research be publicised to the HSE or wider health community in a manner that will optimise impact on health policy and/or practice?
The word limit is **600 words**.

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

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

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

For book and printed source citations:

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

Research Team

Principal Investigator's Role
Outline the role of the PI in this project on a day-to-day basis including the amount of time to be dedicated to working on this project, either as a percentage or a proportion of a full time equivalent (FTE). The word limit is **250 words**.

Co-Applicant's Role
Outline the role of all Co-Applicants in this project on a day-to-day basis including the amount of time to be dedicated to working on this project either as a percentage or as a proportion of a full time equivalent (FTE). The word limit is **250 words**.

Collaborator's Role
Include details of all collaborators involved in the project and state their contribution to the project. The word limit is **100 words**.

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

Infrastructure & Support

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

Access to a Clinical Research Infrastructure
Related to the question above, applicants are asked to provide specific details where they have accessed or plan to access the support of a Clinical Research Facility/Centre, Clinical Trials Unit, Imaging Centre or similar facility nationally and/or internationally, at study design and/or implementation phase. The following information must be provided:

- Name and address of the Facility/Centre
- Information on the nature and stage/s of the input/advice/collaboration/service;
- Rationale for the choice of facility/centre

- Information on the costs of providing the service/input, setting out where this is provided in-kind, from additional funding or requested from the project budget
- Any issues related to feasibility

The word limit is **600 words.**

Applications involving patients who do not detail such input, advice and/or support (and where this expertise is not clearly evident within the applicant team) should justify why they have chosen not to access such support.

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

Project Budget

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

The maximum total value of an award is €330,000 (for PoR, HSR and PHR panels) inclusive of overhead contribution. **There is no set limit per annum** therefore the proposed budget per annum should reflect anticipated annual costs.

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

A **full detailed breakdown** of **costings** and **justification for all funding** is required for items listed under each subheading. 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.
d) Student Stipend	The HRB student stipend is €16,000 per annum (tax exempt) as recommended by current IUA scales
e) Student Fees	A contribution to fees for students registered for a higher degree will be paid at maximum value as the 2008/2009 fee levels or lower for the duration of the award. Applicants should liaise with their Host Institution's Research Office for fee levels. Please note only personnel in receipt of a student stipend are eligible to receive a student fee contribution.
2. **Running Costs**	For all costs required to carry out the research including materials

	and consumables, survey costs, travel for participants, transcription costs etc. Maintenance costs of animals are allowed only for pre-clinical animal models only*. Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, Clinical Research Facilities support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Access to Clinical Research Form' upload. The following costs are ineligible and will not be funded: training courses/workshops for funded research personnel, inflationary increases, cost of electronic journals. Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
3. **Equipment**	Funding for small items of equipment can be included in this section. The maximum amount that can be requested for equipment **over the lifetime of the award** is €2,000. Stand-alone computers will not be funded. All costs must be inclusive of VAT, where applicable.
4. **Dissemination Costs**	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan.
5. **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 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for **laboratory based research** and 25% of Total Direct Costs if **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.

* The maximum HRB allowable per diem rates for the maintenance of the most common strains of small animals are: mice (€0.50), other laboratory rodents (€1) and rabbits (€2) All per diem rates are inclusive of VAT at 21.5%. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis.

Other Funding Sources
Please indicate if you have submitted this, or a similar application, to another HRB scheme or funding body previously. If this application has been submitted elsewhere, please indicate which HRB scheme or funding body, project title, result of submission or when outcome is expected and the amount of award.

Give details of any other financial support available for this or any other related project e.g. existing national or international studies. Indicate project title, funding agency or sponsor and the amount of award. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review.
The word limit is **1000 words**.

Ethical Approval and Use of Animals
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).
Experiments should use the smallest possible number of animals to investigate the research question, and should ensure that distress and suffering are avoided wherever possible. If your project involves the use of animals (pre-clinical models only), applicants must give sound scientific reasons for their use, and explain why there are no realistic alternatives in their proposals. A copy of a valid animal licence must be submitted to the HRB at time of award.

Applicants should allow sufficient time to obtain ethical approval and or animal licenses. It is suggested that ethical approval and or animal licenses are sought in parallel with submission of an application to the HRB.

Sponsorship for Clinical Trial Applications

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HRB cannot take on the role of sponsor. Plans for appropriate sponsorship arrangements must be included in the application i.e. Letters of Support must be provided from sponsors or potential sponsors.

Nomination of International Peer Reviewers

You are allowed to nominate a maximum of **two individuals that could act as peer reviewers** for your proposal in the HRB international peer-review process. The individuals nominated by you may or may not be contacted by the HRB. Please refer to HRB Conflict of Interest Policy for further details.

Submission of Applications

The deadline for submission of complete applications is 30 October 2013 at 13.00.

1. After successful validation the Principal Investigator 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 Principal Investigator 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 Principal Investigator 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 decision of the HRB Board in respect of any grant application is final and cannot be appealed or reviewed.

Appendix IB: Detailed Guidance on the Application Form for the Definitive Intervention (DI) panel

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 Principal Investigator must create the application but it can then be jointly completed with named co-applicants.

- Principal Investigators can register on GEMS and they will receive an email to confirm their registration and log in details. The Principal Investigator can then add information on their contact and CV details in 'Manage My Details' section of GEMS.
- Principal Investigators 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. Applicants must select PoR, HSR, PHR or DI from among the four choices of HRA 2014 Panels, based on which is the most appropriate to review the application (please read the Remit of the HRB Grant Selection Panels on Appendix II page 29 of the Guidance Notes). This Appendix covers information for the DI panel application form. If you are submitting an application to the PoR, PHR or HSR panel you should read the relevant guidance for completing that application form for these panels, provided in Appendix IA:

- Patient-Oriented Research panel
- Population Health Research panel
- Health Services Research panel
- **Definitive Intervention panel**

One the PI selects the Panel 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 PI must satisfy the conditions of this check list.

The Principal Investigator will be then able to start the application. Further details for completing each of the main sections of application form is provided below:

Host Institution and Signatory Notification

Host Institution
The Host Institution for the HRB award is a recognised research institution in the Republic of Ireland. This is normally that of the Principal Investigator but it may be another organisation/institution designated by the research team, where it is clearly justified. A list of the Host Institutions recognised by the HRB at the time of this call going live is included in Appendix X or as a PDF attachment in GEMS. Identify a Host Institution from this list and type it into GEMS 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.

If you wish to propose a host institution which is not on the HRB list you are advised contact the HRB at **gemshelp@hrb.ie.**

Signatory Notification (within Host Institution)
Once the Host Institution is selected at the initial stages of application creation this will allow the 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 Principal Investigator's intention to submit an application to the HRA 2014. 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 PI and if they have any queries or clarifications they can engage directly to resolve them with the PI. 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.

Principal Investigator, Co-Applicants and Collaborators contact details

Principal Investigator's Details
Details are requested about the Principal Investigator including their position and status (contract or permanent) and whether they are seeking salary-related costs.
Please note that a letter of support from the Host Institution must be provided if a Principal Applicant is on contract position (see section 2.5 at page 10 for more details)

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

Co-Applicants
The Principal Investigator can add up to 5 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 PI 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 PI to participate on the application

as a co-applicant. Registered Co-applicants can then manage/update their contact details and CVs in 'Manage My Details' and they 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 can 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.
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 (see section 2.5 at page 10 for more details)

Prior to 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) **Publications and Funding Record (**List of all publications in peer-reviewed journals and details of any past or current grants held (including HRB grants) where the applicant has acted as Principal Investigator or Co-Applicant) under 'Manage my Details' section of GEMS and this information will be automatically included in any application that involves this individual.

Collaborators Details
The Principal Investigator 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 PI. The PI 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. Electronic signatures are acceptable on letters/forms that are uploaded on GEMS.

Project Details

Project Title
This should be descriptive and concise and should reflect the aim of the project.

Project Duration and Start date

Please indicate the expected length of the proposed project in months (maximum duration is 36 months). The anticipated start date should be realistic and would typically be between 3-6 months after HRB Board approval (June 2014).

Project Lay Summary
This lay summary is similar to the project abstract in that you are asked to describe what you propose to do, say why you think it is important to complete this piece of work and how you are going to go about conducting, analysing and drawing conclusions from the research. The difference is that it needs to be written as a plain English summary such that it is clear, easy to understand, and is easily accessible to a lay audience. The lay summary may be used when providing information to the public with regards to the variety of research funded by the HRB and may be posted on the HRB website. The word limit is **300 words**.

Project Abstract
This should be a succinct summary of the proposed research. The aims and hypotheses of the project should be conveyed with clarity. The objectives of the project and what the work is expected to establish should be described. Ideally it provides a clear synopsis of your proposal and should set the research proposal in context. The word limit is **300 words**.

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

Project Description

You are advised to ensure that your application is focused and that sufficient evidence is provided to enable the international peer reviewers and grant selection Panel to reach a considered judgement as to the quality of your research proposal, its significance and its feasibility.

The Project Description should include:

- Background to the Area, Relevance and Rationale
- Overall Aim
- Objectives and Deliverables (including Gantt chart or alternative)
- Evidence from pilot and feasibility studies
- Research Design and Methodological approach
- Project Management
- Patients, User and Stakeholder Involvement
- Dissemination and Knowledge Exchange Plan

Background to the Area, Relevance and Rationale
Describe the background to the research proposal and detail the size and nature of the issue to be addressed.

- What is the problem to be addressed? Include a clear explanation of the key research questions and the impact on the target group and how this research would fill a demonstrable evidence gap. Why is the research important in terms of improving the health of the public and/or patients and/or health policy?
- Why is this intervention needed now? Indicate the necessity for the research, both in terms of time and relevance. Please refer to any Cochrane systematic review and/or any other important work supporting your application and discuss the proposed intervention

in light of this review(s). If not relevant reviews have been conducted please explain in details your strategy for this intervention.

- Does the intervention have a coherent theoretical basis?
- Is it the right time to conduct this study with regard to the current knowledge of the intervention and the current use of existing technologies?
- Will the results be generalizable beyond the research setting of the study in a way that will maximize the impact of the results?

The word limit is **1200 words**.

Overall Aim

Please state the overall aim of the research project. 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 (e.g. PhD submission) and roles and responsibilities of the Principal Investigator team etc.

Evidence from pilot and feasibility studies

Before addressing the research plan you must clearly provide relevant information from previously conducted pilot and feasibility studies. Describe clearly but succinctly the work that was carried out, when, on what groups and settings and what was learned that facilitated the finalization of the protocol for the final definitive study. Provide assurances that you are confident that the intervention can be implemented as intended.

The word limit is **2000 words**

Research Design and Methodological Approach

Describe and justify the design chosen for the proposed intervention, the methods you plan to use and the rationale of your choice. Please address the following:

- What is the proposed study design?
- What are the planned interventions?
- Have you fully described 'usual care'?
- What are the proposed practical arrangements for allocating participants to study groups?
- What are the proposed methods for protecting against sources of bias?
- How variable is the intervention – between sites, over time etc?
- Are there aspects of context and/or the environment which may impact on the evaluation being undertaken?
- What are the planned inclusion/exclusion criteria?

- What is the proposed duration of intervention period?
- What is the proposed frequency and duration of follow up?
- Discuss the reliability and validity of all study instruments and scales
- What are the proposed primary and secondary outcome measures?
- How will the outcome measures be measured at follow up?
- Will health service research issues be addressed? Justify inclusion/exclusion of health economics and quality of life measures. If these measures are to be included full details should be given including power calculations
- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include for both control and intervention groups, a brief description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate
- What size of the difference is the trial powered to detect?
- What is the planned recruitment rate? How will the recruitment be organised? Over what time period will recruitment take place? What evidence is there that the planned recruitment rate is achievable?
- Are there likely to be any problems with compliance? On what evidence are the compliance figures based?
- What is the likely rate of loss to follow up? On what evidence is the loss to follow-up rate based?
- How many centres will be involved?
- Has acceptability testing been considered?
- What is the proposed type of analyses?
- What is the proposed frequency of analyses?
- Are there any planned subgroup analyses?

The word limit is **5000 words**

Notes:

- The HRB encourages the development and application of agreed standardised sets of outcomes, known as 'core outcome sets', such as those reported by the COMET (Core Outcome Measures in Effectiveness Trials) Initiative.
- You are strongly advised to seek advice and input from an experienced research design and statistics expert in advance of submitting your application. Discrepancies and incorrect approaches in this section represent the most common source of feedback in unsuccessful HRB applications.
- Explain in detail how new techniques and/or or high-risk studies will be managed and suggest alternative approaches should these fail.
- Where new methods are being developed, arrangements for establishing validity and reliability should be described. Examples of non-standard questionnaires, tests, etc. should accompany the application or their content be clearly indicated.
- Useful links and resources are summarised in Appendix IV.

Project Management

Please describe the arrangements for day to day management of the trial. The role of each applicant team and research personnel member and collaborators should be clearly outlined for all aspects of the study including recruitment, randomisation, delivery of intervention, follow-up, data entry, data management and analysis. Does the team include people with experience of successfully running large intervention studies? Has adequate statistical advice been sought and incorporated? Describe any oversight, advisory or governance structures that are crucial to delivery of the project and to oversee and monitor the evaluation, including a trial steering committee or data safety and monitoring committee if applicable. Provide terms of reference for these groups and proposed membership.

Outline the processes that will be put in place to ensure that the overall project is well managed, commenting on project management, meetings schedules, financial management etc.

The word limit is **1500 words**.

Patients, User and Stakeholder Involvement

Please describe if patients and/or users and/or stakeholders have been actively involved in the preparation of this application and/or will be involved in the proposed research and if so provide details of the individuals/groups and the ways. If this is not applicable to your application please explain why. The word limit is **600 words**.

Note: The HRB encourages the involvement of consumers and patient advocate groups with the aim of better research and protocol design and greater usability of both the research project and its findings.

Dissemination and Knowledge Exchange Plan

Include a clear dissemination and knowledge exchange plan to indicate how information will be disseminated during and after your research. Who are the various audiences and communities that need to be targeted if these results are to have any impact? What is your dissemination plan to address this? Describe academic publication plans and/or plans for technology transfer. Describe how the findings of this research be publicised to the HSE or wider health community in a manner that will optimise impact on health policy and/or practice?

The word limit is **600 words**.

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

References

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

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

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

Research Team

Principal Investigator's Role
Give an outline the role of the PI in this project on a day-to-day basis including the amount of time to be dedicated to working on this project, either as a percentage or a proportion of a full time equivalent (FTE).
The word limit is **250 words**.

Co-Applicant's Role
Give an outline the role of all Co-Applicants in this project on a day-to-day basis including the amount of time to be dedicated to working on this project either as a percentage or as a proportion of a full time equivalent (FTE).
The word limit is **250 words**.

Collaborator's Role
Include details of all collaborators involved in the project and state their contribution to the project.
The word limit is **100 words**.

Personnel
Give full details of all personnel to be funded through this project. State the percentage of time each person will spend on the project and describe what aspects of the proposed research they will be involved in over the lifetime of the project. If funding is requested for known personnel, please include the following details: Name, address, present position, academic qualifications, professional qualifications.
Give a detailed justification for the nature of the research personnel relative to the scale and complexity of the project.

Infrastructure & Support

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

Access to a Clinical Research Infrastructure
Related to the question above, applicants are asked to provide specific details where they have accessed or plan to access the support of a Clinical Research Facility/Centre, Clinical Trials Unit, Imaging Centre or similar facility nationally and/or internationally, at study design and/or implementation phase. The following information must be provided:

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

- Rationale for the choice of facility/centre;
- Information on the costs of providing the service/input, setting out where this is provided in-kind, from additional funding or requested from the project budget
- Any issues related to feasibility

The word limit is **600 words**.

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

Note: Applications involving patients who do not detail such input, advice and/or support (and where this expertise is not clearly evident within the applicant team) should justify why they have chosen not to access such support.

Project Budget

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

The maximum total value of an award is €800,000 (for DI panel) inclusive of overhead contribution. **There is no set limit per annum** therefore the proposed budget per annum should reflect anticipated annual costs.

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

A **full detailed breakdown** of **costings** and **justification for all funding** is required for items listed under each subheading. 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.
d) Student Stipend	The HRB student stipend is €16,000 per annum (tax exempt) as recommended by current IUA scales
e) Student Fees	A contribution to fees for students registered for a higher degree will be paid at maximum value as the 2008/2009 fee levels or lower for the duration of the award. Applicants should liaise with their Host Institution's Research Office for fee levels. Please note only personnel in receipt of a student stipend are eligible to receive a student fee contribution.
2. **Running Costs**	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription

	costs etc. Maintenance costs of animals are allowed only for pre-clinical animal models only*. Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, Clinical Research Facilities support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Access to Clinical Research Form' upload. The following costs are ineligible and will not be funded: training courses/workshops for funded research personnel, inflationary increases, cost of electronic journals. Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
3. **Equipment**	Funding for small items of equipment can be included in this section. The maximum amount that can be requested for equipment **over the lifetime of the award** is €2,000. Stand alone computers will not be funded. All costs must be inclusive of VAT, where applicable.
4. **Dissemination Costs**	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan.
5. **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 30% of Total Direct Modified Costs (TDMC excludes student fees, equipment and capital building costs) for **laboratory based research** and 25% of Total Direct Costs if **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.

* The maximum HRB allowable per diem rates for the maintenance of the most common strains of small animals are: mice (€0.50), other laboratory rodents (€1) and rabbits (€2) All per diem rates are inclusive of VAT at 21.5%. Maintenance costs for research involving large animals or other types of small animals must be agreed on a case-by-case basis.

Other Funding Sources
Please indicate if you have submitted this, or a similar application, to another HRB scheme or funding body previously. If this application has been submitted elsewhere, please indicate which HRB scheme or funding body, project title, result of submission or when outcome is expected and the amount of award.

Give details of any other financial support available for this or any other related project e.g. existing national or international studies. Indicate project title, funding agency or sponsor and the amount of award. Failure to disclose accurately or fully may result in your application being deemed ineligible and withdrawn without further review.
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 (see section 2.5 at page 10 for more details)
The word limit is **1000 words**.

Ethical Approval and Use of Animals
Ethical approval is required for all research work funded by the HRB that involves human participants, human material (including tissue) or animals. If your project involves the use of animals (pre-clinical models only), applicants must give sound scientific reasons for their use, and explain why there are no realistic alternatives in their proposals. Experiments should use the smallest possible number of animals to investigate the research question, and should ensure that distress and suffering are avoided wherever possible. A copy of a valid animal licence must be submitted to the HRB at time of award.

Applicants should allow sufficient time to obtain ethical approval and or animal licenses. It is suggested that ethical approval and or animal licenses are sought in parallel with submission of an application to the HRB.

Sponsorship for Clinical Trial Applications

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HRB cannot take on the role of sponsor. Plans for appropriate sponsorship arrangements must be included in the application i.e. Letters of Support must be provided from sponsors or potential sponsors.

Nomination of International Peer Reviewers

You are allowed to nominate a maximum of **two individuals that could act as peer reviewers** for your proposal in the HRB international peer-review process. The individuals nominated by you may or may not be contacted by the HRB. Please refer to HRB Conflict of Interest Policy for further details.

Submission of Applications

The deadline for submission of complete applications is 30 October 2013 at 13.00.

6. After successful validation the Principal Investigator may submit the application. It will then be routed to the designated signatory at the Host Institution for their approval.
7. If a signatory rejects the application the Principal Investigator will be notified, along with any feedback the signatory has supplied.
8. The application can then be re-submitted; it will be returned to the signatory and will continue through the approval process as before.
9. On completion of the final approval by the Host Institution signatory, a grant application number is assigned to the application.
10. 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 Principal Investigator 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 decision of the HRB Board in respect of any grant application is final and cannot be appealed or reviewed.

Appendix II: Remits for the HRA 2014 Grant Selection Panels

The details below are not exhaustive but should serve as a useful guide to applicants in considering relevance and eligibility for this scheme and in selecting the most appropriate Panel. Applications will be reviewed upon receipt by HRB staff based on the criteria below. In the case of any queries regarding appropriateness or eligibility, staff will consult with the appointed international Chairs of the relevant Panels before making a final decision.

Patient-Oriented Research

Patient-oriented research is defined as research conducted with human subjects, or on material of human origin, such as tissues, specimens and cognitive phenomena. The research generally involves patients, samples and/or data from patient and other people who are not patients (e.g. healthy volunteers).

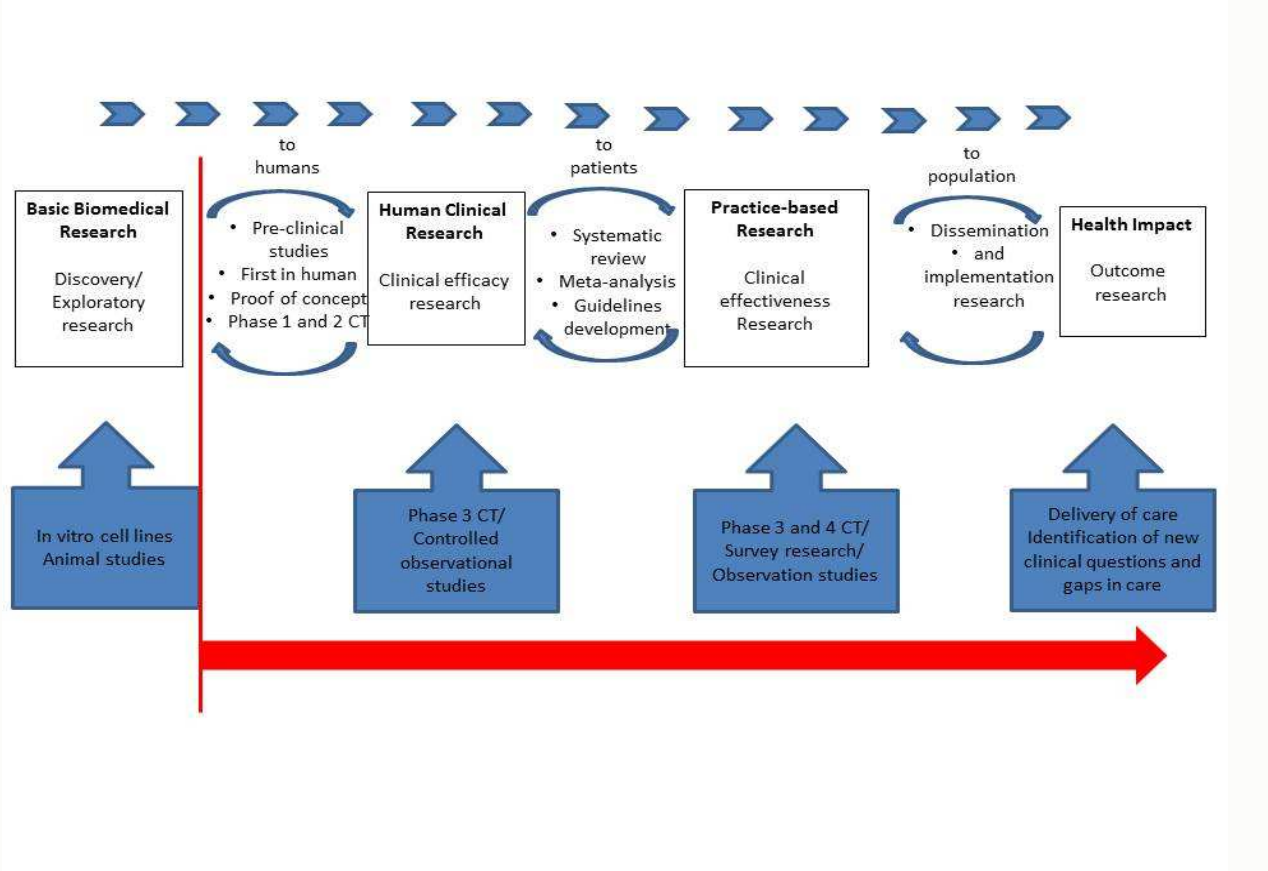
- The HRB will not support basic biomedical research or work involving cell lines, animals or their tissue. However, the HRB will consider research projects that involve pre-clinical studies, on the understanding that pre-clinical studies represent an important stage of research that occurs before testing in humans to find out if a drug, treatment or procedure is likely to be useful. Such studies gather data on efficacy, feasibility, toxicity, safety and supports patient eligibility criteria. They typically involve research using particular species of animals and in such cases the HRB will consider supporting animal work. However, appropriate evidence must be provided in the application setting out the case for the pre-clinical study, to justify the choice of species in a manner which resembles the human condition in aetiology, pathophysiology, symptomatology and response to therapeutic intervention and describing how the pre-clinical study correlates and aligns with the planned future stages of the research study in humans. In some pre-clinical studies, due to the species-specific nature of the clinical product (e.g., some vector-expressed human transgenes or human derived cellular products) testing in animals would not prove informative or appropriate so alternative in vitro pre-clinical studies models can be proposed, but again detailed justification must be provided.

- If the work involves biomarkers:

  - Research that aims to elucidate mechanisms underpinning disease or to identify risk factors for disease or prognosis (including searching for biomarkers) is out of remit.
  - Research that tests whether the application of new knowledge can improve treatment or patient outcomes, and has obvious potential benefit within 5 years, is within remit. This might include the validation of known biomarkers and/or other known risk factors which have an established relationship with a disease or clinical condition, to refine and test novel therapeutic strategies.

Only applications submitted to the PoR panel which begin with research activity to the right of the red line in diagram in the figure below will be considered within remit for this panel.

Figure 1: Continuum from research to impacts and outcomes



Population Health Research

Research with the goal of improving the health of the population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status or through the identification of effective interventions for improving health status and reducing health inequalities.

The emphasis of the PHR panel is on prevention of disease, promotion of health and wellbeing and the reduction of inequalities in health. It focuses on the health of the whole population or on defined sub-groups and aims to generate evidence that is highly relevant to improving the health and wellbeing of the public.

Note: There is significant overlap between clinical medicine and population health approaches. For the purposes of this scheme, if you are submitting a science- or medically-driven proposal where the emphasis is on disease diagnosis, treatment or care of an individual or a patient group, you should submit your application to the patient-oriented panel.

Applications submitted to the PHR panel should focus on issues such as:

- Macro-level socio-economic determinants of health (the influence of social and economic policies on health)

- Individual-level socio-economic determinants of health (the relationships between access to the resources of society such as housing, income, employment, food security and health)
- Individual behavioural/lifestyle factors such as smoking, nutrition, alcohol and substance abuse, physical activity and sexual behaviour and their impact on health
- Occupational and environmental determinants
- The health of populations over the lifecourse (e.g., Birth, child and adult development and ageing)
- Health of specific population groups (e.g. children and youth, people with disabilities, older adults, migrant populations)
- Gender issues and health
- Health protection, promotion, health education and intervention programmes
- Genetic epidemiology
- Prevention and control
- Monitoring and surveillance of population health

Health Services Research

Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of healthcare and ultimately health and well-being.

This Panel will consider applications focusing on the planning, management, organisation, financing, purchasing and provision of health and social care services. It will address aspects of the quality of services, access and equity in provision, relevance and appropriateness to the needs of individuals and communities, effectiveness and efficiency, workforce capacity and capability issues and how services are experienced. Applications focusing on the three main dimensions of quality – patient safety, patient experience and effectiveness of care – are particularly welcome.

Applications focusing on issues such as the following are welcome;

- Access to services
- Strategic management of waiting times
- Health service planning
- Health service delivery and organization
- Integration of care
- Evaluation of health services interventions
- Delivery and organization of hospital and primary health care
- Community-based care (long-term care, home care)
- Chronic disease prevention and management
- Citizen engagement
- Health professional influences on health care
- Public and private health care sectors
- HR and financing of health services
- Health policy and systems management
- Health ethics and law

- Health informatics
- Pharmacoepidemiology
- Quality of life and quality of care
- Health systems and policy

Definitive Interventions

Research with the goal of providing high-quality evidence on the efficacy, effectiveness, costs and broad impact of an intervention in humans with tangible benefits to patients, people's health and/or health services. The research must address questions of direct relevance to the improvement of patient care, the health of the public and/or health services and should have the strong potential to have immediate use in everyday practice and policy and decision makers.

Applicants submitting applications to this panel must be able to provide evidence from previously conducted pilot and feasibility studies. Pilot and feasibility studies play an important role in providing information for the planning and justification of definitive trials (and evaluative studies). Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can work together. They are focused on the processes of the main study to ensure recruitment, randomization, treatment and follow-up assessments all run smoothly. They resemble the main study in many respects including an assessment of the primary outcome. Feasibility studies are pieces of research done before a definitive study in order to answer the question "Can this study be done"? They are used to estimate important parameters that are needed to design he main study.

It will be expected that applicants will be able to provide detailed evidence on the following types of issues in order to apply to the HRA-DI panel:

- Initial data for the primary outcomes measure in order to finalise a sample size calculation for a larger trial;
- Information on the integrity of the study protocol, including inclusion/exclusion criteria, storage and testing of equipment and materials, training of staff involved in the intervention, pilot data collection methods etc;
- Evidence of having piloted data collection forms questionnaires, patient information documents, consent forms etc;
- Evidence of willingness of participants to be recruited/randomised and evidence of testing of the randomization procedure;
- Evidence of willingness of clinicians to recruit participants;
- Information on consent rates, follow-up rates, response rates, adherence/compliance rates, ICCs in cluster trials etc;
- Information on number of eligible patients, carers or other appropriate participants;
- Characteristics of the proposed outcomes measure including the reliability of the outcome and the feasibility of measurement;
- Availability of data needed for usefulness and limitations of a particular database;
- Time needed to collect and analyse data;

Appendix III: **Checklist for Intervention studies (randomised and non-randomised designs)**

Regardless of whether your project involves an evaluation of a simple or a complex intervention and regardless of whether it is based on a randomised or a non-randomised design, the review Panels will take into account the following key questions when assessing the application. It is recommended that you use this checklist as a guide before finalising and submitting your application. It is also recommended that you seek advice from individuals or centres that are experts in study design and statistics before submitting your application.

1. **The need for the study**

- What is the problem to be addressed?
- What is/are the principal research question(s) to be addressed?
- Does your intervention have a coherent theoretical basis?
- Does the existing evidence – ideally collated from systematic reviews – suggest that it is likely to be effective or cost effective?
- What outcome are you aiming for and how might this bring about change?
- Can it be implemented in a research setting?
- Describe any risks to the safety of participants involved in the trial

2. **The Proposed Study**

- What is the proposed study design? e.g. randomised or non-randomised, experimental or observation design, pragmatic or equivalence, conventional parallel group RCT as opposed to cluster, factorial or stepped-wedge design etc
- What are the planned interventions?
- Have you fully described 'usual care'?
- What are the proposed practical arrangements for allocating participants to study groups? E.g. Randomization method. If stratification or minimization are to be used, give reasons and factors to be included
- What are the proposed methods for protecting against sources of bias? e.g. Blinding or masking. If blinding is not possible please explain why and give details of alternative methods proposed, or implications for interpretation of the trial's results
- How variable is the intervention – between sites, over time etc?
- Have you adequately described the context and the environment in which the evaluation is being undertaken?
- What are the planned inclusion/exclusion criteria?
- What is the proposed duration of intervention period?
- What is the proposed frequency and duration of follow up?
- Have you discussed reliability and validity of all study instruments or scales?
- What are the proposed primary and secondary outcome measures?
- How will the outcome measures be measured at follow up?
- Will health service research issues be addressed? Justify inclusion/exclusion of health economics and quality of life measures. If these measures are to be included full details should be given including power calculations

- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include for both control and intervention groups, a brief description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate
- It is important to give the justification for the size of the difference that the trial is powered to detect. Does the sample size calculation take into account the anticipated rates of non-compliance and loss to follow-up given below?
- What is the planned recruitment rate? How will the recruitment be organised? Over what time period will recruitment take place? What evidence is there that the planned recruitment rate is achievable?
- Are there likely to be any problems with compliance? On what evidence are the compliance figures based?
- What is the likely rate of loss to follow up? On what evidence is the loss to follow-up rate based?
- How many centres will be involved?
- Has any pilot or feasibility work been conducted to be confident that the intervention can be implemented as intended?
- Has acceptability testing been considered? What user involvement is there in the study?
- Is your study ethical?
- Are there any local or other contextual issues that need to be factored into the design?

3. Data Collection and Management

- What are the arrangements for day to day management of the trial? e.g. Randomisation, data handling, and who will be responsible for coordination?
- What arrangements have you put in place to oversee and monitor the evaluation?
- Is there a need for a trial steering Panel or a data safety and monitoring Panel.
- What is the proposed type of analyses?
- What is the proposed frequency of analyses?
- Are there any planned subgroup analyses?
- Will the design chosen really enable you to draw conclusions about effectiveness?

Appendix IV: **References/Useful Links**

"Developing and Evaluating Complex Interventions" by MRC, UK
www.mrc.ac.uk/complexinterventionsguidance

"Using natural experiments to evaluate population health interventions: **Guidance for producers and users of research evidence"** by MRC, UK **www.mrc.ac.uk/naturalexperimentsguidance**

Consort 2010 Statement: updated guidelines for reporting parallel group randomised trials
www.consort-statement.org

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

SQUIRE Guidelines: provides a framework that authors can use when developing proposals or writing research articles about quality improvement
www.squire-statement.org

HIQA Guidelines for the Economic Evaluation of Health Technologies in Ireland (2010)
http://www.hiqa.ie/publication/guidelines-economic-evaluation-health-technologies-ireland

HIQA Guidelines for the budget Impact Analysis of Health Technologies in Ireland (2010)
http://www.hiqa.ie/publications/guidelines-budget-impact-analysis-health-technologies-ireland

HIQA Guidelines for Evaluating the Clinical Effectiveness of Health technologies in Ireland (2011)
http://www.hiqa.ie/system/files/HTA-Clinical-Effectiveness-Guidelines.pdf

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

COMET (Core Outcome Measures in Effectiveness Trials) Initiative: development and application of agreed standardised sets of outcomes, known as 'core outcome sets' **http://www.comet-initiative.org/**

Health Research Board Clinical Research Facility, **Galway http://www.nuigalway.ie/hrb_crfg/**

Wellcome Trust – Health Research Board Dublin Centre for Clinical Research
http://www.molecularmedicineireland.ie/page/g/s/45

Clinical Research Support Centre (Northern Ireland)
http://www.crsc.n-i.nhs.uk/

Health Research Board Clinical Research Facility, Cork
http://www.ucc.ie/en/crfc/

Clinical Research Facility, University College Dublin
http://www.ucd.ie/medicine/ourresearch/researchcentres/ucdclinicalresearchcentre/

Wellcome Trust-Health Research Board Clinical Research Facility, St James's Hospital
http://www.sjhcrf.ie/default.aspx

Clinical Research Centre, Royal College of Surgeons in Ireland,
http://www.rcsi.ie/index.jsp?p=331&n=696

Irish Clinical Research Infrastructure Network
http://www.molecularmedicineireland.ie/page/g/s/44

Centre for Advanced Medical Imaging, St James' Hospital Dublin
http://www.3tcentre.com/

All Ireland Hub for Trials Methodology Research
http://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/TheAll-IrelandHubforTrialsMethodologyResearch/

Appendix V: Host Institutions approved by the HRB

No	Title	Forename	Surname	Email	Organisation
1	Ms	Eilish	Hardiman	ceo@amnch.ie	Adelaide and Meath Hospital (incorporating the National Children's Hospital)
2	Dr	Bernadette	Flanagan	bflanagan@allhallows.ie	All Hallows College
3	Ms	Kitty	O'Connor	catoconnor@rcsi.ie	Alpha One Foundation
4	Ms	Lorna	Walsh	lwalsh@ait.ie	Athlone Institute of Technology
5	Mr	Liam	Duffy	liamduffy@beaumont.ie	Beaumont Hospital
6	Dr	Julianne	Byrne	jbyrne@boyneresearch.ie	Boyne Research Institute Limited
7	Mr	Peter	Murphy	pmurphy.brainwave@epilepsy.ie	Brainwave-The Irish Epilepsy Association trading as Epilepsy Ireland
8	Dr	Michelle	Share	sharem@tcd.ie	Children's Research Centre
9	Dr	Gayle	Kenney	gayle.kenney@cuh.ie	Children's University Hospital
10	Ms	Mary	Desmond	desmondm@cope-foundation.ie	COPE Foundation
11	Dr	Niall	Smith	niall.smith@cit.ie	Cork Institute of Technology
12	Ms	Avril Anne	O'Sullivan	Avril.Osullivan@HSE.IE	Cork University Hospital
13	Ms	Marie	O'Dowd	research@cystinosis.ie	Cystinosis Foundation Ireland Limited
14	Dr	Anna	Clarke	anna.clarke@diabetes.ie	Diabetes Ireland Research Alliance Limited
15	Dr	Ana	Terres	ana.terres@dcu.ie	Dublin City University
16	Professor	June	Nunn	june.nunn@dental.tcd.ie	Dublin Dental University Hospital
17	Dr	John	Donovan	john.donovan@dit.ie	Dublin Institute of Technology
18	Mrs	Imelda	Quinn	imelda.quinn@duchenne.ie	Duchenne Ireland
19	Ms	Stefanie	Ratzky	Stefanie.ratzky@dkit.ie	Dundalk Institute of Technology
20	Ms	Gillian	Davidson	gillian.davidson@esri.ie	Economic and Social Research Institute
21	Dr	Patrick	Nash	patrick.nash@hse.ie	Galway & Roscommon University Hospitals Group
22		A	Research Office	ResearchOffice@gmit.ie	Galway Mayo Institute of Technology
23	Dr	Suvi	Dockree	dockrees@headway.ie	Headway (Ireland) Limited
24	Dr	Sinead	Walsh	swalsh@irishcancer.ie	Irish Cancer Society
25	Mr	Vincent	McCabe	vmccabe@irishheart.ie	Irish Heart Foundation
26	Dr	Hilary	Dunne	hdunne@isqsh.ie	Irish Society for Quality and Safety in Healthcare
27	Ms	Mary	Collins	ResearchOffice@mic.ul.ie	Mary Immaculate College
28	Ms	Linda	Glennie	lindag@meningitis.org	Meningitis Research Foundation
29	Ms	Ann-Marie	Coen	annmarie@mdi.ie	Muscular Dystrophy Society of Ireland Limited
30	Dr	Harry	Comber	h.comber@ncri.ie	National Cancer Registry Ireland
31	Ms	Eileen	Williamson	ewilliamson@ucc.ie	National Suicide Research Foundation
32		A	Research Office	hrb@nuigalway.ie	National University of Ireland, Galway

33				research.support@nuim.ie	National University of Ireland, Maynooth
34	Ms	Mo	Flynn	mflynn@olh.ie	Our Lady's Hospice Limited
35	Ms	Colleen	Spence	colleen.spence@qub.ac.uk	Queen's University
36	Ms	Joanna	Holly	joannaholly@rcpi.ie	Royal College of Physicians of Ireland
37	Ms	Clare	Muckian	resofficeadmin@rcsi.ie	Royal College of Surgeons in Ireland
38	Ms	Mette	Jensen Kavanagh	mette.jensen@hse.ie	Sligo General Hospital Research & Education Foundation Limited
39	Dr	Aine	Kelly	aine.kelly@sjog.ie	St John of God's Research Foundation Limited
40	Dr	Michele	Glacken	mglacken@stangelas.nuigalway.ie	St. Angela's College Sligo Limited
41	Dr	Regina	McQuillan	rmcquillan@sfh.ie	St. Francis Hospice Dublin
42	Ms	Muireann	O'Briain	mobriain@stjames.ie	St. James's Hospital
43	Ms	Edwina	Hogan	ehogan@stjames.ie	St. James's Hospital Foundation Limited
44	Mr	Frank	Byrne	fbyrne@stpatsmail.com	St. Patrick's Hospital Foundation
45	Professor	Jim	Lucey	jlucey@stpatsmail.com	St. Patrick's University Hospital
46	Ms	Grainne	McGettrick	gmcgettrick@alzheimer.ie	The Alzheimer Society of Ireland
47	Dr	Jacinta	Kelly	jacinta.kelly@ncrc.ie	The Childrens Medical and Research Foundation
48	Ms	Marion	Bruce	mbruce@haughton-institute.ie	The Haughton Institute for Graduate Education & Training in the Health Sciences
49	Professor	Luke	Clancy	lclancy@tri.ie	TobaccoFree Research Institute Ireland Limited
50	Dr	Camilla	Kelly	research.office@tcd.ie	Trinity College Dublin
51	Dr	David	O'Connell	D.OConnell@ucc.ie	University College Cork
52		A	Research Office	research@ucd.ie	University College Dublin
53	Professor	Fionnuala	McAuliffe	fmcauliffe@nmh.ie	National Maternity Hospital
54	Dr	Sinead	O'Doherty	sinead.odoherty@ul.ie	University of Limerick
55		Research	Office	Ulster-submission@ulster.ac.uk	University of Ulster
56	Ms	Susie	Cullinane	scullinane@wit.ie	Waterford Institute of Technology