MEDICAL RESEARCH CHARITIES GROUP/HEALTH RESEARCH BOARD

MRCG/HRB Joint Funding Scheme 2016

Guidance Notes

Key Dates & Times

HRB Call Announcement	**23 September 2015**
Charity Application Open* (check with individual charity)	**Early October 2015**
Charity Application Closing Date* (check with individual charity)	**Mid November 2015**

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MRCG/HRB Joint Funding Scheme 2016

Guidance Notes

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1. Introduction

The Medical Research Charities Group (MRCG) was founded in 1998 with the aim of supporting charities in Ireland to increase both the quality and quantity of healthcare research being done in Ireland. The MRCG represents the joint interests of charities specialising in restoring health through medical research, diagnosis and treatment and, where possible, the prevention of disease. Since 2006, the work of the MRCG has been supported by the Health Research Board (HRB) through co-funding of research projects. The level of funding is currently at €800,000 per annum. The HRB is the lead agency in Ireland supporting research linked to health and social care. During the period of the Strategic Business Plan 2016-2020, the HRB will continue to work in partnership with others to accelerate the translation of research into real benefits for people and play a key role in health system innovation, transformation and economic development.

This innovative joint funding scheme allows members of the MRCG to support research addressing their research strategy, where they might otherwise not be in a position to finance the full cost of that research. To date, 87 projects have been jointly funded by member charities and the HRB in seven rounds. While no differentiation is made between charities or disease areas, the scheme has been particularly beneficial for rare diseases where research being undertaken internationally may be limited and where charities wishing to contribute to the research agenda need to fund research projects led from outside Ireland.

MRCG and HRB have developed guidelines for competitive peer review to ensure that high quality and innovative research projects receive funding through this scheme. The partnership with the HRB supports the building of research funding capacity in Irish research charities and ensures that all elements of this research funding programme are operated at the highest standards of best international practices.

The MRCG and HRB are now inviting applications for its 2016 call of the MRCG/HRB Joint Funding Scheme.

1.1 Objective

The MRCG/HRB Joint Funding Scheme aims to fund researchers and research teams to conduct internationally competitive and innovative research in **areas of strategic relevance to each individual charity**. The value of the application to the charities' strategic aims must be clearly demonstrated. Projects are expected to create new knowledge and evidence of benefit to health or healthcare.

1.2 Scope

This scheme provides funding for clearly defined research projects in areas of strategic relevance to each individual charity. MRCG/HRB awards will be up to a maximum total award value of **€300,000** for projects from 12 up to 36 months. Applications for funding of the Irish arm of an international study are within scope; funding may depend on funding of the main study. Funding outside of Ireland **may be allowable** where there is no established research capacity in Ireland (e.g. for the case of rare diseases).

Following a review of the scheme, the joint scheme now allows for co-funding of a single project by either up to four Irish MRCG charities or by one Irish MRCG charity and an international charity. Guidance notes on the application form are available in Appendix 1.

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, health service research, behavioural science, qualitative research methodologies, psychology, sociology etc. should be included as Co-Applicants or as official Collaborators. From past experience the MRCG/HRB strongly recommends that applications involving randomised controlled trials include input from experienced trialists. For studies that require a lot of coordination applicants should consider the appointment of a study manager or coordinator (for small studies this may be one of your Co-Applicants, rather than a dedicated post).

The MRCG/HRB expects that applicants will collaborate, where appropriate, with partner organisations, such as universities, hospitals, health agencies, local government and or voluntary organisations. The HRB promotes the active involvement of members of the public in the research that we fund (see section 2.5 for further details) and as such wishes to encourage participation within the co-applicant and/or collaborator team (e.g. community groups, NGOs, patient groups) as a fundamental way of delivering meaningful public involvement.

2.1 Principal Investigator

The Principal Investigator (PI) will serve as the primary point of contact during the review process and during the award. 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 contract governing the award.

The Principal Investigator must

- Hold a post that covers the duration of the award in a recognised Research Institution as an independent investigator, **or**

- be a contract researcher recognised by the Research 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 Research Institution upon receipt of the MRCG/HRB award as a contract researcher as defined above. The Principal Investigator does not necessarily need to be employed by the Research Institution at the time of the application submission

The Principal Investigator must demonstrate that they have the skills, knowledge and supports necessary to direct the proposed research and to be actively engaged in carrying the research through to completion. Generally this means that the PI will:

i. Show appropriate evidence of expertise matched to the nature and context of the project;
ii. Show evidence of achievement as an independent researcher in their chosen research field by:
    a) Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs such as published book chapters, reports to government and/or any other relevant outputs that have resulted in a significant impact in their field.
    b) Demonstrating record of independence by showing that they have secured at least one peer-reviewed research grant for a research project/s, as either the lead applicant or a co-applicant. Funding received for travel to seminars/conferences and/or small personal bursaries will not be considered in this regard.
iii. Show evidence that they possess the capability and authority to mentor, manage and supervise less experienced researchers and to manage relationships with co-applicants, collaborators and the host institution.

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

Only one application per Principal Investigator to this scheme will be considered. Where the PI is based outside of Ireland, where possible they should seek Co-applicants or Collaborators in Ireland in order to build capacity here.

2.2 Co-Applicant

A Co-Applicant has a well-defined, critical and substantial role in the proposed research stated explicitly in the application. Each Co-Applicant should view the application form and approve content prior to submission. A Co-Applicant may receive funding for items such as running costs and personnel but will not receive support towards his/her own salary if they are in salaried positions. However, Co-Applicants can request their own salary, depending on their role and percentage of time dedicated to the research project, for the duration of the award if they are contract independent investigators **(up to a maximum of 5 Co-Applicants can be listed)**.

The terms of any co-application should be determined early and relevant agreements should be in place by the onset of the project. The MRCG/HRB advise that consideration should be given to issues such as governance arrangements, intellectual property rights, reporting and access to data and samples when working up co-application agreements.

2.3 Official Collaborator

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 access to samples, vulnerable population groups, healthy volunteers or patients, data, databases or a link to an existing national or international study (e.g. an existing cohort or longitudinal study) are an integral part of the proposed project, evidence of commitment and access must be demonstrated by having the key Gatekeeper of this data or study included as a Collaborator.

In addition, each official collaborator must complete a **Collaboration Agreement Form.** A template Collaborator agreement form is available and this must;

- Detail the full nature of the collaboration and how the Collaborator will be involved in the proposed research and specifically the value they will add
- Confirm the individual or organisation's commitment to the proposed project
- Identify the value, relevance and possible benefits of the proposed work to the Collaborator
- State the period of support
- Detail how the results of this collaboration will be disseminated
- Details of the costs requested, where relevant, and appropriate justifications

The terms of any collaboration should be determined early and relevant agreements should be in place by the onset of the project. The HRB advise that consideration should be given to issues such as relative responsibilities, governance arrangements, intellectual property rights, reporting and access to data and samples when working up collaboration agreements.

2.4 Funded Personnel

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. Alignment between personnel requested and the proposed project should be given strong consideration. Reviewers will thoroughly assess the level of baseline experience matched with the supervisory and up-skilling arrangements proposed in scoring the proposal.

Unlike the HRB's fellowships programmes, this scheme is not framed as a training initiative. Where junior personnel registered for a higher degree are proposed to work on projects, Principal Investigators must carefully consider the complexity, scale, objectives and dependencies of the project and the skills, expertise and experience level required to carry it out, especially if involving one or more PhD student(s). In such instances, PIs are also strongly encouraged to think about the suitability of such projects for PhD students, in terms of delivering a clearly identifiable original research project or the potential difficulties in clustering various pieces of work packages for a PhD thesis.

2.5 Public Involvement in Research

The MRCG/HRB promotes the active involvement of members of the public in the research that we fund. We use the INVOLVE UK (www.invo.org.uk) definition of the term 'public' which includes patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Public involvement, as defined here, is distinct from and additional to activities which raise awareness, share knowledge and create a dialogue with the public and it is also distinct from recruitment of patients/members of the public as participants in research.

'Public involvement' represents an active partnership between members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research.

Involving members of the public in research can improve quality and relevance. It can:

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

In addition to improving relevance and quality of research, it ensures that research is influenced by broader principles of citizenship, accountability and transparency.

In the application, you are asked to describe any public involvement in your research throughout the various stages of research design, conduct, analysis and dissemination. We recognise that the nature and extent of active public involvement is likely to vary depending on the context of each study or

award. A number of useful resources for guiding researchers on public involvement in research are provided in Appendix 3.

2.6 Host Institution

Host Institution for the award is a recognised research institution approved by the HRB under its Host Institution Policy. It is typically that of the Principal Investigator but it may be another organisation/institution designated by the research team, where it is clearly justified. Please note that **the HRB has introduced a new Host Institution Policy with effect of 1 July 2015**. Research performing organisations wishing to submit an application need to comply with the new policy.

Note: Host Institution Letter 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 Host Institution is typically located in the Republic of Ireland. Funding researchers in Host Institutions outside of Ireland may be allowable where there is no established research capacity in Ireland (e.g. for the case of rare diseases)

- For international Host Institutions that are **public or private universities** a warrant should be given at application stage that they can comply with HRB terms and conditions (available on the HRB web page at www.hrb.ie For international Host Institution that are **not public or private universities**, the Host Institution will agree that as part of the acceptance documentation if successful they will have to provide information as per the HRB Host Institution application form.

2.7 Access to Clinical Research Infrastructures

Applications availing of the advice, trial and data management services and/or other forms of support from a Clinical Research Facility/Centre (CRF/CRC), other infrastructure unit (e.g. Centre for Applied Medical Imaging, CSTAR) or a research network (e.g. All-Ireland Trials Methodology Research Network) are required to provide additional information detailing the scope and nature of the engagement (this include national facilities and/or international facilities and Units/networks where justified). An Infrastructure Agreement form will be requested as part of the application addressing the nature/scope of the service or collaboration, the rationale behind the choice of facility/centre/network and any costs associated with the project (including those provided as in-kind contributions). Applications proposing research with patients, which do not detail advice and/or support from a CRF/CRC/CTU, will be asked to justify why they have not done so.

3. Funding

MRCG/HRB awards will be up to a maximum total award value of **€300,000** for projects from 12 months up to 36 months. Eligible costs include personnel costs, student stipend and fees, direct running costs and dissemination costs.

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

Note: The scheme does 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 fellowship 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 and Review Procedure

4.1 Application Procedure

All applications must be made to the MRCG-registered research charity on or before their own set closing dates. All application documents must be completed in font Calibri Size 11. It is the responsibility of the Principal Investigator to ensure that applications are completed in full and all the necessary documentation is received by the charity on or before the closing dates indicated.

Note: ***Please note each document will have a size limit of 2MB.***

4.2 Review Procedure

The MRCG/HRB is committed to an open and competitive process underpinned by international review. Each charity will conduct a peer review process by soliciting reviews of proposals from at least three international experts **based outside of the Republic of Ireland** in the subject area of the proposed research. Reviews from experts will be collated and forwarded to applicants.

4.2.1 Response to reviewers

The Principal Investigator with the support of his/her team will be provided with a time-limited opportunity to respond to peer-reviewers comments. The peer-reviewers comments will be made available to PIs by email. Each PI and team will have **14 calendar days only** to submit their response to the charity they applied to, and the response has a maximum word count of **2000 words**. The response will be used by the charity to inform their short-listing process, and in case of short-listed applications will be provided to members of the Panel in advance of their face-to-face meeting alongside the application and the peer-reviewers' comments.

There is no obligation to submit a response but this phase of the assessment process is extremely important and the response may play a critical role in whether a proposal eventually gets recommended for funding or not. It provides an opportunity to address any factual errors, conceptual misunderstandings or differences of opinion that can be perceived as weakness or concerns. It also provides the PI and team with an opportunity to take on board any constructive feedback that may help to improve the application, if funded, or future grant applications.

The response should be succinct yet clear and comprehensive. It should acknowledge and/or address all of the significant concerns and/or weaknesses described in the reviewer's feedback. If the applicant team disagrees with a reviewer's statement they should explain why and provide additional information. If the applicant team cannot address an issue, they should at least acknowledge it. Responses that could be seen as argumentative should be avoided. Remember that peer reviewers and panel members volunteer their own time in reviewing grant applications.

Principal Applicants should ask a colleague to read the reviewers' critiques and the responses prior to resubmission, to confirm that they have addressed the critique in a way that is informative and constructive.

4.2.2 Short-Listing by MRCG-registered Charity

Each charity will conduct an internal selection process. Whilst individual charities may have additional criteria, the **relevance of the application in addressing the strategic aims of the charity** will be a core criterion. The charities' justification for selection of applications and their strategic plan will be forwarded alongside the nominated applications to a MRCG/HRB-jointly nominated selection Panel.

4.2.3 Panel meeting

This Panel will have access to the original applications, charity background information on work and priority areas, international peer reviewer comments, applicant's response to reviewers' comments and charities' justification for application selection and will be asked to make final recommendations on those projects that will be funded. They will base their recommendations on the following key assessment criteria:

- Scientific Quality and Innovation (50% of 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.
    - Quality of the PPI approach.
    - 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 of the proposed research.
- Expertise and Research Environment (20% of marks)
    - 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.
    - Experience of the applicant(s) in the proposed area of research and with the proposed methodology.
    - Qualifications of the applicant(s), including training, experience and independence (relative to career stage).
    - 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.
    - Availability and accessibility of suitably qualified personnel, facilities and infrastructure required to conduct the research.
    - Suitability of the environment to conduct the proposed research.
    - 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.
    - The extent to which the research team have demonstrated the potential for collaboration with key organisations responsible for implementing or applying the findings;
    - The extent to which public involvement is incorporated into the research proposal;
- Relevance and impact of the research on the goal(s) of the charity (30% of marks)
    - The need for research in this area. Is there similar or complementary research underway elsewhere?
    - The importance of doing the work now. Whether the proposal realistically sets out the ultimate potential benefits with respect to improving human health
    - To what extent the proposal will contribute, directly or indirectly, to relieving the burden of disease
    - Whether the proposed research likely to generate results which users will be interested in taking up and if so are the plans for dissemination appropriate

The identity of the experts who participate in the peer review process shall remain confidential and shall not be disclosed to the Principal Investigators. A summary of Panel member's comments and the panel discussion comments will be issued to the Principal Investigator following the conclusion of the review process.

4.2.4 Award Contracts

Host Institutions of successful applications will be offered multi-party contracts between the HRB, the MRCG partner(s) and the approved Host Institution setting out the respective roles and responsibilities of the parties and governing the research project. The HRB Terms and Conditions will govern the award in its entirety. Additional special conditions may apply.

5. Timeframe

23 September 2015	Opening of HRB Call
from late September 2015	Charity Call Opening Date *(check with individual charity)*
Mid- November 2015	Charity Call Closing Date *(check with individual charity)*
June 2016	Joint Committee Meeting will take place in June 2016 with a view to making final recommendations to the Board of the HRB in June 2016
July 2016	Following Board approval of the recommendations, successful applicants will be notified of their success by early July 2016
August 2016	Contracts will be issued in August 2016 with a view to beginning the research projects from September 2016
September 2016	Research Project Start Date

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 provide all supporting documentation within the 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 1: Guidance on the Application form

These notes must be read in conjunction with the Application Form and are designed to help you provide the required information. Please ensure that you complete the Application Form in full. Do not leave a question blank, but if you feel that a question is not applicable to you please state that this is the case. ***Please note each document (Application Form, Signature Page, Supporting Figures, Gantt chart etc.) will have a size limit of 2MB.***

Project Title (mandatory, maximum 20 words)
This should be both clearly descriptive and concise and should reflect the aim of the project.

SECTION 1: DETAILS OF PRINCIPAL INVESTIGATOR AND CO-APPLICANTS

1.1 Principal Investigator Details

Includes name, contact information, host institution, present position and profession.

1.2 Co-Applicant Details

Includes name, contact information, host institution, present position and profession.

1.3 Host Institution for the award

This institution is normally that of the Principal Investigator but it may be another organisation/institution designated by the research team, where this is clearly justified. The funders must be fully satisfied that the institution can account appropriately, over time, for any funding awarded. You are requested to state the name of institution and to provide the name and contact details of either the Dean of Research/CEO/equivalent authorised personnel of the institution in your application.

Please note that **the HRB has introduced a new Host Institution Policy with effect of 1 July 2015**. Research performing organisations wishing to submit an application need to comply with the new policy.

SECTION 2: PROJECT DESCRIPTION

2.1 Project Lay Summary

This summary is similar to the project abstract in that you are asked to describe what you propose to do, to say why you think it is important to complete this piece of work and how you are actually going to go about conducting the research. This summary needs to be written in plain English such that it is clear, easy to understand, and is easily accessible to a broad lay audience. This 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 and/or the charity website. The word limit is **300 words**.

2.2 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**.

2.3 Keywords (maximum five keywords)
Please choose up to five keywords that specifically describe your area of research.

Relevance of research to strategic aims of the charity or charities Please set out the relevance of your application in addressing the strategic aims of the charity or charities (in the case that two charities are co-funding) and why the charity/charities should select your application to bring forward to the MRCG/HRB-jointly nominated selection panel. Where available, refer specifically to the strategic plan of the charity/charities you apply to, and to any other relevant strategy documents.

2.5 Project Description
The Project Description* should include the following:

- *Current knowledge and background to the area of the proposed research. Description of pilot work already undertaken, if relevant*
- *Overall Aim*
- *Objectives and Deliverables*
- *Relevance and Importance*
- *Research Design and Methodological approach*
- *Project Management (including Gantt chart or alternative)*
- *User and Stakeholder involvement*
- *Dissemination and Knowledge Exchange Plan*

*Any figures to support the project description must be provided in a *single additional document* up to a maximum file size of 2MB.

2.5a Current Knowledge, Background to the area
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 realized. Please provide a clear explanation of the problem to be addressed and 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 the health and wellbeing and who will benefit from this research. The word limit is **1200 words**.

2.5b Overall Aim
Please state the overall aim of your project. The word limit is **100 words**.

Objectives and deliverables

Please add at least 3 individual objectives. Objectives should be SMART (specific, measurable, achievable, realistic and time-bound). For each objective please list a subset of deliverables which will be used to measure progress. Note that the stated objectives and deliverables will be used to monitor progress throughout the lifetime of the award. Timelines should be set against objectives/deliverables in your Gantt chart. The word limit is **60 words for each objective and 150 for deliverables**.

You must provide 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. The Gantt chart should be provided as a separate file with a maximum file size of 2MB.

2.5c 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, feasibility or are carrying out the Irish arm of an international clinical trial study you should review **the MRC Guidelines on Evaluating Complex Interventions, the checklist provided for Intervention Studies in Appendix 2 and the CONSORT checklist highlighted in Appendix 3**.
- 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 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

[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

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.
- The HRB-Trial Methodology Research Network (HRB-TMRN) mission is to strengthen the methodology and reporting of trials in health and social care on the island of Ireland so that they become more relevant, accessible and influential for patients and other service users, practitioners, policy makers and the public. We suggest that they be contacted at an early stage regarding methodology research relevant to trials www.hrb-tmrn.ie .
- 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 3.

The word limit is **4500 words**

2.5d Project Management

Please describe how the project will be managed. The role of each team member should be clearly outlined. Describe any oversight, advisory or governance structures that are crucial to delivery of the project, including the trial steering committee and the 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**.

2.5e Public Involvement in the Research Project

The MRCG/HRB promotes the active involvement of members of the public in the research that it funds where the term 'public' includes patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. The MRCG/HRB recognises that the nature and extent of active public involvement is likely to vary depending on the context of each study. Please provide details of where there has been public involvement in the preparation and/or design of this application and/or provide details of proposed future public involvement in later stages (e.g., conduct, analysis and/or dissemination). Provide information on the individuals/groups and the ways in which they will be involved. If you feel that this is not applicable to your application you are asked to explain why. The word limit is **600 words**. A number of useful links are included in Appendix 3.

2.5f Impact Statement

Please provide details on the likely impact of this study on patients, public and/or the healthcare systems. The word limit is **600 words.**

2.5g Arrangements for Sample Collection for Biobanking

If your application includes an element of biobanking, please describe how you will ensure good practice for biobanking components in this project, with particular regard to quality of sample collection, processing, annotation and storage, and describing data protection measures where appropriate. Please reference relevant guidelines/standards you will use. Some useful links are in Appendix 3. The word limit is **400 words.**

2.5h Potential Risks and Ethical Concerns

Please address any potential risk and/or harm to the safety of the patients or participants in the study, if relevant, and highlight any potential ethical concerns during this study and/or at follow-up stage, even if not part of this application, and how you propose to deal with them. The word limit is **400 words.**

2.5i Compliance with Data Protection Regulations

Please provide comments on how your study complies with national and/or EU Data Protection Regulations, if relevant, especially where the study involves the transfer of data outside of the EU. The word limit is **300 words.**

2.5j 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 publications plans and/or plans for technology transfer. Can any of the findings of this research be publicised to the HSE or wider health community? The word limit is **600 words**.

Note: 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 committee to reach a considered judgement as to the quality of your research proposal, its significance and its feasibility.

2.6 References cited in the project description (maximum 30)

This section of your proposal should demonstrate that you are familiar with recent published research and other scholarly activity related to the proposal. It is through the inclusion of up-to-date references that you can demonstrate your awareness of the current state of knowledge in your chosen discipline. Please use the convention in the example when entering references:

Smyth, B.P. & O'Brien, M. (2004) Children Attending Addiction Treatment Services in county Dublin, 1990-1999. *European Addiction Research,* 10(7455) pp. 68-74.

SECTION 3: DETAILS OF RESEARCH TEAM

3.1 Principal Investigators Role

Give an outline of the role of the PI in the project on a day to day basis including amount of time to be spent working on the project either as a percentage or proportion of a full time equivalent (FTE).

3.2 Co-Applicants Role

Give an outline of the role of the Co-Applicants in the project on a day to day basis including amount of time to be spent working on the project either as a percentage or proportion of a full time equivalent (FTE). Describe the specific contribution and responsibilities of the Co-Applicant.

3.3 Collaborators Role

Include details of all collaborators involved in the project and state their contribution to the project.

3.4 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.

SECTION 5: INFRASTRUCUTRE AND SUPPORT

4.1 Host Institution Infrastructure and Support

Describe the infrastructure, facilities, specialist expertise and other support available at the Host Institution and/or at other sites where the research will be conducted. Please include details of critical supports in areas such as statistics, 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**.

4.2 Access to 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/services of a Clinical Research Facility/Centre, Clinical Trials Unit, Imaging Centre or Research Network (e.g. All Ireland Trials Methodology research Network) at study design and/or implementation phase. The following information must be provided:

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

Where applicable a signed **Clinical Research Infrastructure Agreement Form** (Appendix 1 of the Application Form) must be provided. Failure to provide Clinical Research Infrastructure Agreement Form(s) will result in the application being deemed ineligible. Electronic signatures are acceptable.

SECTION 5: PROJECT DURATION AND BUDGET

5.1 Project Duration and Budget total

Please indicate the expected length of the proposed project in months and provide a summary and justification of the costs and duration associated with the project. The minimum duration is 12 months and the maximum is 36 months. It is important to note that the budget requested and award duration must reflect the scale and nature of the proposed research.

The maximum total value of an award is €300,000. **There is no set limit per annum**.

5.2 Project budget

Use Table 1 to provide a **summary of the Total Costs** requested and Table 2 to justify each amount requested.

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 Research Institution before completing this section of the form. The MRCG/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 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. **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. 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. If requesting pension costs linked to Circular 6/2007, please provide details as justification for the request.
d) Student Stipend	The HRB student stipend is €16,000 per annum (tax exempt) as recommended by current IUA scales.
e) Student Fees	Fees for EU nationals will be covered. Applicants should liase with their Research Institution's Research Office for fee levels. Please note only personnel in receipt of a 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, the purchasing, transport, maintenance or disposal of animals, survey costs, travel for participants, transcription costs etc. 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. 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. 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. 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.
3. 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.

5.3 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 longitudinal study. Indicate project title, funding agency or sponsor and the amount of award.

Failure to disclose accurately or fully will result in your application being deemed ineligible and withdrawn without further review.

SECTION 6: ETHICAL AND REGULATORY APPROVAL, AND USE OF ANIMALS

Ethical approval is required for all research work funded by the MRCG/HRB that involves human participants, human material (including tissue) or animals. In addition, Clinical Trial Approval from the Health Products Regulatory Authority is required for trials involving medicinal products. Necessary authorisations for trials involving medical devices differ depending on the device. An animal licence is required for projects involving animals.

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, applicants must give sound scientific reasons for their use, and explain why there are no realistic alternatives in their proposals.

Give details of need for Research Ethics approval, animal licence requirement, and regulatory approval. Applicants are responsible for ensuring that all necessary approvals are in place and submitted to the MRCG/HRB prior to the start of the research. Applicants should allow sufficient time to obtain these as a copy of any of these approvals must be submitted to the HRB before the initiation of the award. It is suggested that these are sought in parallel to the submission of the application to the charity.

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.

SECTION 7: PRINCIPAL INVESTIGATOR AND CO-APPLICANT CVs AND COLLABORATOR PROFILES

7.1 Principal Investigator CVs

The CV templates provided must be used for the Principal Investigator. The CV template includes sections on career profile, publication and funding records. CVs can be a maximum of 5 pages and should be broken down as follows: Section 1 (max 2 pages) + Section 2 (max 1 page) + Section 3 (max 2 pages)

7.2 Co-Applicant CVs

The CV templates provided must be used for any Co-Applicants. The CV template includes sections on career profile, publication and funding records. CVs can be a maximum of 5 pages and should be broken down as follows: Section 1 (max 2 pages) + Section 2 (max 1 page) + Section 3 (max 2 pages)

7.3 Collaborator Profile

Provide Collaborator details including name, present position, and contact information**.** With regard to Collaborator Publications and Funding Record, where applicable please provide **five most relevant publications** in peer-reviewed journals and give details of any **past or current grants** held (including MRCG or HRB grants) relevant to this application where the collaborator has acted as Principal Investigator or Co-Applicant.

In addition, each official Collaborator must complete a **Collaboration Agreement Form.** A template is made available and this must:

- Detail the full nature of the collaboration, how the Collaborator will be involved in the proposed research and specifically the value he/she will add
- Confirm the individual or organisation's commitment to the proposed project
- Identify the value, relevance and possible benefits of the proposed work to the Collaborator
- State the period of support
- Detail how the results of this collaboration be disseminated

Note: Research Institution Letter 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 and signed by the Head of School/Research Centre/Hospital must include the following information; [*Research Institution – insert name*] which is the research institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognised by the research institution upon receipt of the MRCG/HRB 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.

SECTION 8: NOMINATION OF INTERNATIONAL PEER REVIEWERS

You are allowed to nominate a maximum of **two individuals that could act as peer reviewers** for your proposal. The individuals nominated by you may or may not be contacted. Nominated reviewers should be individuals of international repute in the research area or methodology outlined in your proposal and should be **based outside of the Republic of Ireland**. In making your nomination(s) please bear in mind that you cannot recommend an individual individual who was involved in the preparation of the application, who stands to benefit directly if the application was funded or rejected, with whom you have collaborated over the past 10 years, or with whom you have a close personal or professional relationship.

Submission

Please ensure that you have completed all the relevant sections of the application form. Once you have submitted your application, you cannot edit or unsubmit it. All applications must be submitted to the MRCG-registered research charity on or before their own set closing dates.

Signature Page

All applications for funding must be signed by the Principal Investigator and the Dean of Research/CEO/equivalent authorised personnel of the Research Institution using the signature page provided in Appendix 3. ***All signatures must be originals. Electronic versions of signatures are not acceptable (Size limit of 2MB).***

Appendix 4 includes a warrant, which must be signed by **Host Institutions outside of Ireland** if applicable.

Checklist for submission

For all applications

Application form	
Figures supporting project description (1 document)	
Gantt chart	
Signature page	

Where applicable

Collaboration Agreement Form	
Infrastructure Agreement Form	
Letters of support	
Warrant for international Host Institutions only	

Appendix 2: 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 3: References/Useful Links

DEVELOPING AND EVALUATING STUDIES

"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

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/

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

REPORTING

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

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

CLINICAL RESEARCH INFRASTRUCTURES/SUPPORTS

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

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

HRB-Clinical Research Coordination Ireland
http://www.crci.ie

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

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/

Health Research Board Trials Methodology Research Network
http://www.hrb-tmrn.ie

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

Centre for Support and training Analysis and Research (CSTAR)
http://www.cstar.ie

BIOBANKING

OECD Guidelines on Human Biobanks and Genetic Research Databases
http://www.oecd.org/science/biotech/44054609.pdf

ISBER Best Practices for Repositories
http://www.isber.org/?page=BPR

Molecular Medicine Ireland Biobanking Guidelines
http://www.molecularmedicineireland.ie/page/g/t/103

NCI Best Practices for Biospecimen Resources
http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf

RESEARCH PRIORITIES &PUBLIC INVOLVEMENT IN RESEARCH

INVOLVE UK website for resources on Public and Patient Involvement in research
http://www.invo.org.uk

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

"Public and Patient Involvement (PPI) in Research" by Irish Health Research Forum
http://www.mrcg.ie/assets/23/2A2C32C1-AC5A-7DF1-9CEDCA21B1745ED7_document/Forum_PPI_Doc_5-15.pdf

"Developing a Process to Prioritise Research Questions for Policy, Practice and Services" by Irish Health Research Forum
http://www.mrcg.ie/assets/22/2A2EF907-DB60-A760-E5BE77CD3D23A278_document/Forum_12-5-15_Briefing_Paper.pdf

Database of Uncertainties about the Effects of Treatments (UK DUETS)
http://www.nice.org.uk/about/what-we-do/evidence-services/database-of-uncertainties-about-the-effects-of-treatments-uk-duets

The James Lind Alliance Priority Setting Partnerships
http://www.lindalliance.org/Patient_Clinician_Partnerships.asp

The Value+ Toolkit: For Patient Organisations On Meaningful Patient Involvement:
http://www.eu-patient.eu/Documents/Projects/Valueplus/Value+%20Toolkit.pdf