



Canadian Chiropractic
Guideline Initiative

ADVANCING EXCELLENCE IN CHIROPRACTIC CARE

National Chiropractic Practice-Based Research Network

PROPOSAL GUIDELINES

Applications for seed funds for local PBRNs 2017

Due: January 20, 2017 by 11:59 pm

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GLOSSARY

Applied Dissemination¹: a term which refers to the process of disseminating information about an existing program, process, concept or knowledge and skills, and applying that information in a different context.

Capacity and capacity building²: in knowledge exchange, capacity is the set of skills, structures, and processes, as well as the organizational culture that allows, encourages, and rewards knowledge exchange. The capacity of decision-making and research organizations is built to achieve knowledge exchange in order to make decisions on the basis of research and other evidence.

Diffusion³: the process by which an innovation is communicated through certain channels over time among members of a social system.

Dissemination²: goes well beyond simply making research available through the traditional vehicles of journal publication and academic conference presentations. It involves a process of extracting the main messages or key implications derived from research results and communicating them to targeted groups of decision makers and other stakeholders in a way that encourages them to factor the research implications into their work. Face-to-face communication is encouraged whenever possible.

End of grant knowledge translation⁴: consists of diffusion, dissemination and application of research findings.

Evidence based practice⁵: practitioners make practice decisions based on the integration of the research evidence with clinical expertise and the patient's unique values and circumstances.

Integrated knowledge translation⁶: a collaborative way of doing research, researchers and research users work together to shape the research process- starting with collaboration on setting the research questions, deciding the methodology, being involved in data collection and tools development, interpreting the findings and helping disseminate the research results. This approach, also known by such terms as collaborative research, action-oriented research, and co-production of knowledge, should produce research findings that are more likely be relevant to and used by the end users.

Knowledge⁴: primarily scientific research.

Knowledge exchange⁴: collaborative problem-solving between researchers and decision makers that happens through linkage and exchange. It involves interaction between decision makers and researchers and results in mutual learning through the process of planning, producing, disseminating, and supplying existing or new research in decision-making.

Knowledge transfer⁶: the process of getting knowledge used by stakeholders.

Knowledge translation⁶: is a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system.

This process takes place within a complex system of interactions between researchers and knowledge users which may vary in intensity, complexity and level of engagement depending on the nature of the research and the findings as well as the needs of the particular knowledge user.

Knowledge translation research⁷: Studying the determinants of knowledge use and effective methods of promoting the uptake of knowledge (contributing to the theory of KT).

Participatory research⁷: the systematic enquiry, with the collaboration of those affected by the issue being studied, for the purpose of education and taking action or effecting social change.

Research utilization⁴: process by which specific research-based knowledge is implemented in practice.

Synthesis⁶: synthesis in the context of knowledge translation means the contextualization and integration of research findings of individual research studies within the larger body of knowledge on the topic. A synthesis must be reproducible and transparent in its methods, using quantitative and/or qualitative methods. It could take the form of a systematic review, follow the methods developed by the Cochrane Collaboration, result from a consensus conference or expert panel or synthesize qualitative or quantitative results. Realist syntheses, narrative syntheses, meta-analyses, meta-syntheses and practice guidelines are all forms of synthesis.

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1. Philanthropic Foundations Canada. Grantmaker Resources. Glossary of Terms. Montreal.
2. Canadian Health Services Research Foundation. Tools to Help Organizations Create, Share, and Use Research.
3. Greenhaigh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: Systematic review and recommendations. *Milbank Quarterly* 2004;82(4):581-629.
4. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof* 2006;26(1):13-24.
5. Straus SE. Evidence-based medicine : how to practice and teach EBM. 3rd ed. Edinburgh ; New York: Elsevier/Churchill Livingstone, 2005.
6. Canadian Institutes of Health Research. About Knowledge Translation CIHR-IRSC.
7. Participatory Research at McGill. Participatory Research Mission. Montreal, 2008.

Application Checklist

- The research question concerns practice-based research in chiropractic.
- The research proposal is in line with the mission of the CCGI and the PBRN:
 - *to facilitate dissemination and implementation within the chiropractic profession of clinical practice guidelines and best practice likely to have significant and measureable impact on the health of Canadians;*
 - *to conduct research in the area of musculoskeletal disorders associated with high societal disease burden, and explore the opportunities for impact across multiple non-communicable chronic diseases.*
- The principal investigator holds an appointment at an academic institution.
- The principal investigator has formal research training (PhD or the equivalent)
- The project leader is a doctor of chiropractic (DC) or a DC enlisted in a master's or doctoral program.
- Ethical approval for the project has been/will be sought at the local level.
- The 1-page mid-term written report must be submitted by October 1, 2017.
- The final 2-page written report must be submitted by March 31, 2018.
- Recipients are encouraged to prepare a poster or a presentation to be submitted to an appropriate conference or meetings. Submission of a manuscript of the final study results is also strongly encouraged.
- Completed application form including, the title of the project, the names and affiliations of the investigators, and the contact details of the team members.
- Abstract (max. 350 words) and Research proposal, no longer than 3,000 words
- Budget justification
- Short CV of each member of the team (training and grants, publications, presentations in the past 5 years)
- Two letters of support
- Signature of each member of the team
- Application receipt by 20 January, 2017 11:59 pm (electronic version of application)

Applications submitted to: Heather Owens, CCGI research manager, howens@chiropractic.ca

Questions/assistance with protocol development: Heather Owens, howens@chiropractic.ca

Time Line

January 20, 2017	Application submission deadline (11:59 pm deadline)
January 25, 2017	Compiled applications sent to reviewers
February 27, 2017	Reviewers meeting
March 15 , 2017	Notice of decision released by email
April 1, 2017	Payment period commences
Oct 1, 2017	Mid-term study report submission
March 31, 2018	Final study report submission

Goals of the Project and Expectations

Goals

The overall aim of the national chiropractic practice-based research network is to two-fold: 1) to facilitate dissemination and implementation within the chiropractic profession of clinical practice guidelines and best practice likely to have significant and measurable impact on the health of Canadians and 2) to conduct research in the area of musculoskeletal disorders associated with high societal disease burden, and explore the opportunities for impact across multiple non-communicable chronic diseases.

Expectations

Applicants must provide a convincing case that the proposed project will increase the flow and uptake of information between researchers, clinicians, educators, patient groups and/or other stakeholders concerned with chiropractic care.

The principal applicant and project leader will be responsible for providing **a total of two study reports**. The first report is a **1-page written** mid-term report on the progress made to date. The second will be a **2-page final written** report on the work accomplished and final study results and an accounting of expenditure. Members are strongly encouraged to submit a manuscript to the Journal of the Canadian Chiropractic Association (JCCA) and to prepare a poster presentation to be displayed at an appropriate conference or meeting at the end of the project. Should the study results be submitted to journal other than the JCCA, successful applicants should agree to submit a commentary (or editorial) to the JCCA as part of their dissemination plan.

All written reports, oral presentations and publications must acknowledge the support of the CCGI, and be sent by email to howens@chiropractic.ca for our files.

Funding

The annual funding envelope for 2016-17 is **\$25,000**. Funding will be awarded to peer reviewed and merit based chiropractic practice-based research projects in line with the CCGI and PBRN mission to disseminate and implement best practices. **Priority in this funding round will be given to projects aimed at developing new PBRNs**. Projects will be funded up to a maximum of **\$12,500**. Any changes to the funding guideline noted above are subject to prior board approval of the PBRN Advisory Committee.

There is one funding opportunity per year, but applications of a suitable standard may be presented in the interim period for consideration. The payment period for the projects is from 1st April 2017 to 31st March 2018.

Projects are expected to be **completed within a year**. However, project leaders are eligible to apply for funding for another project in a subsequent year. Only one project per **project leader** will be allocated for each funding year. Funding for each project is non-renewable, **but a maximum extension of 6 months** will be granted for project activities to be completed.

Funding is expected to cover salary for the research coordinator, as well as any project-related expenses (i.e. consumables such as photocopies, communication, etc.). A budget with detailed justification of all costs is required as part of the application. The budget should exclude costs related to preparing and printing the poster.

Eligibility

The designated ***principal applicant*** (principal investigator) on the grant must hold an appointment at an academic institution and have a PhD or equivalent. The principal applicant has responsibility for the intellectual direction of the proposed research and for financial and progress reporting. A participating applicant may be designated as the ***co-principal applicant*** (co-principal investigator) for their significant contribution to the intellectual direction of the proposed research. The co-principal investigator can be affiliated with another university or clinical institution.

The ***project leader*** is expected to be guided through the process by the ***principal applicant***. Grant applications will be accepted from ***project leaders*** who are chiropractors or masters/doctoral/post-doctoral students from any university or clinical institutions. Project leaders can also be considered as project co-principal investigators, when appropriate. A doctoral or master's or post-doctoral student is ineligible to receive a stipend from the PBRN project if they are receiving any doctoral, master's or post-doctoral award.

Where appropriate, the research team would include:

- Clinician(s) or project leader;
- A doctoral/masters/post-doctoral student
- A clinical supervisor/educator

- A stakeholder/decision maker

It is important to involve patients, carers and the public in health research. Involvement means that “people who use services are active partners in the research process rather than [just] ‘subjects’ of research”¹.

Proposals are eligible if they meet the following requirements:

1. Research focused on chiropractic practice-based research, and in line with the CCGI and PBRN mission, as stated above.
2. Key stakeholders are identified and appropriately engaged in the research from conception through to evaluation and dissemination of results. Partners may include those involved in health care delivery or planning and administration, policy making, not-for-profit organizations, community organizations, patient support groups etc.
3. Include a clear, explicit, and manageable knowledge translation plan, which specifies the intended audience(s), the means of involvement and communication, and the intended post-grant follow-up.
4. Proposed methods for conducting a project must be appropriate, rigorous and feasible; potential problems must be identified and contingencies offered.
5. The scope of proposals should not be so narrow that the results could be meaningful for only a very limited target audience; nor should the scope be so broad that it is impossible to derive meaningful results applicable to real-life situations.
6. All projects must evaluate the impact of their knowledge translation plan by measuring change in clinicians’ practice behaviours, patient-related outcomes, and/or organizational characteristics (as applicable) at the end of their study. A clear description of this evaluation must be included in the research proposal. The National PBRN Advisory Committee has prepared an Outcome Evaluation Framework with suggested measures to assess the impact of knowledge translation interventions, which may be applicable for your study (see Appendix for Framework).
7. Projects favouring the application of knowledge into clinical practice (i.e. steps of the Action Cycle of the KTA model⁵) will be considered eligible for funding. Studies that contribute towards creating 'first generation knowledge' (i.e. basic science projects) are not eligible.

8. Research Ethic Board (REB) approval will be obtained from one of the research team institutions prior to undertaking the project.

NB. Applicants not eligible to apply to REB at an academic institution can contact Mr. Mark Fillery, Research Administrator, Department of Research at CMCC. Please note, it is CMCC policy to charge \$500 for all external applications for REB review. We recommend that applicants considering using CMCC's REB, include cost as a budget expense in their proposal. Please contact Mr. Mark Fillery if you have further questions (mfillery@cmcc.ca).

Application Deadline and Instructions

The deadline for applications is **20 January 2017 at 11:59 pm**. Please submit an **electronic version** of the application to Heather Owens at: howens@chiropractic.ca. **Hard copies are NOT required**. The application consists of:

1. An application form containing:
 - a. Title of the project
 - b. Names and affiliations of the investigators
 - c. Co-ordinates of the team, including e-mail address
 - d. Signature of each member of the research team agreeing to submission of the proposal
 - e. Abstract (max. 350 words) should be submitted as an Additional File
 - f. Proposal (outline below, outline examples in appendix)
 - g. Budget with detailed justification of all costs
2. Short CV for each member of the team
3. Letter of support for clinicians participating as a project leader and applying for stipend.
4. Letter of support from stakeholder organisation(s) for projects conducted within health centres (hospital, rehabilitation facility etc.).

The proposal should be no longer than **3,000 words including tables**. The role of each member of the team should be clearly described e.g. consumer, clinician, project leader, principal applicant. Appendices may only include questionnaires; any additional material will be disregarded. The budget and its justification must be on a separate page and is not included in the word count. Times New Roman, size 12 font and double spacing should be used for the abstract, summary, proposal, and budget justification.

Components of Proposal (systematic reviews, qualitative or quantitative research proposals are acceptable)

1. Study title
2. Background
3. Study objectives
4. Methods
5. Ethical considerations
6. Logistics
7. References
8. Appendices

ALLOWABLE COSTS

The full application must provide a detailed justification of all costs.

The following expenditures will be considered eligible for funding:

- Salaries of research personnel (coordinator, assistant).
- Purchase and maintenance of research equipment and other research tools (e.g., statistical software).
- Student or clinician stipend.
- Regional, national and international networking and exchange activities during the planning and dissemination of the research (e.g. networking, conferences, workshops, meetings, communication and dissemination methods). Eligible activities must involve substantive and meaningful interaction between researchers and stakeholders
- Costs associated with the creation and distribution of communication tools
- Conference registration, travel or accommodation fees for one presenter up to a maximum of 500\$.

IMPORTANT: Make sure your budget accounts for non-discretionary benefits (minimum 18-23% for Employment Insurance, Canada Pension Plan, etc.) for any salaries and/or stipends

NON-ALLOWABLE COSTS

- Stipends/pays for clinicians or clinician to get reimbursed for their time away from clinical work.
- Salaries of PI, investigators, co-investigators, clinicians members of the PBRN
- Ongoing operation of practice
- Patient honorarium Computers, I-pad, I-phone, etc.
- Indirect costs such as administration fees

Review Process

- All eligible applications received by the appropriate deadline date (20 January 2017) will be entered into the competition.
- All members of the PBRN Advisory Committee will receive full copies of each application and a ranking sheet by 25 January 2017.
- Each application will be assigned to three members of the committee for detailed review and presentation during the meeting.
- The PBRN Advisory Committee meeting will be held on 27 February 2017.

In advance of the meeting, reviewers will be required to:

1. Read the **abstracts of each project** and assign a rank. The best project will be ranked 1, next best ranked 2 etc. (number of ranks depends on number of project submitted)
2. **Fully read assigned proposals** (between 3 to 5) and assign one of the following funding decisions: Not funded, Funded with revisions, Funded without revisions.
3. Write a brief justification of the ranking on the ranking sheet.
4. E-mail the completed ranking sheet to Heather Owens by 20 February 2017.

During the meeting

Committee members attending the meeting will be presented with the funding recommendations for each proposal and the justifications. Each study will be discussed and budget reviewed by the three assigned reviewers and other Committee members. A final funding decision will be made collectively by the Committee for each proposal.

Applicants will be informed of the results of the competition as follows:

1. All applicants will be sent a Notice of Decision by email, indicating whether or not their proposal was approved for funding, and the amount awarded by the second week of March 2017.
2. Applicants will receive a Scientific Officer's Report and a copy of all comments from the Committee members by email shortly after receiving their Notice of Decision.

Outcome Evaluation Framework to Assess Knowledge/Beliefs/Barriers and Impact of KT interventions at the Individual & Organizational levels

DOMAINS	OOUTCOME MEASURES
STRUCTURE EVALUATION (process of care)	
Clinician/patient knowledge*	<u>Quantitative</u> <ul style="list-style-type: none"> • Knowledge questionnaire (based on the learning objectives of the KT intervention) to measure change in knowledge regarding a specific content area
Clinician/patient Attitudes, Barriers, utilization*	<u>Survey questionnaires</u> <ul style="list-style-type: none"> • <i>Practice Style Trait Questionnaire</i>¹: to identify the practice style trait of clinicians and their overall attitude towards evidence-based practice • <i>Pain Attitudes and Beliefs Scale</i>^{2,3} • <i>Health Care Providers' Pain and Impairment Relationship Scale (HC-PAIRS)</i>⁴ • <i>E-Base questionnaire incl. EPIC Scale</i>⁵: to measure clinicians' belief in their ability to implement EBP, known as EBP self-efficacy. • <i>Barriers to Research Utilization scale</i> (BARRIERS; Funk et al., 1991; Carson & Plonczynski, 2008 review) • <i>Evidence-Based Practice Questionnaire</i> (Upton & Upton, 2006) • <i>Evidence-Based Practice Attitude Scale (EBPAS)</i> (Aaron 2004, 2007, 2010, 2012; Patterson 2014) • <i>Evidence-Based Practice Attitude and Utilization SurvEy (EBASE)</i> (Leach 2008) • <i>Theoretical Domain Framework (TDF)</i> (Huijg 2014) • <i>Communication Skill</i> (Baig 2009) • <i>SIROP - Engagement</i> <u>Qualitative</u> <ul style="list-style-type: none"> • <i>Theoretical Domains Framework (TDF)</i>⁶ : to identify clinicians' beliefs using interviews or focus groups (Michie 2005; Cane 2012; TDF Series 2012)
Organizational	Survey questionnaires <ul style="list-style-type: none"> • <i>Context Assessment Index (CAI)</i> (McCormack 2009) • <i>Organizational readiness to change assessment (ORCA)</i> (Helfrich, 2009) • <i>Stage of Implementation Completion (SIC)</i> (Chamberlain 2011)

	<p>Framework</p> <ul style="list-style-type: none"> • Consolidated Framework for Implementation Research (CFIR) (Damschroder, 2009) • RE-AIM (reach, efficacy, adoption, implementation and maintenance) (http://RE-AIM.org)
Clinician practice behaviours*	<p><u>Quantitative</u></p> <ul style="list-style-type: none"> • Electronic Health Records (EHRs) • Chart audit of clinician practices <p><u>Qualitative</u></p> <ul style="list-style-type: none"> • PERFECT Tool⁷: standardized semi-structured questions regarding change and reasons for change in clinicians' practice behaviours • Clinical vignettes (behavioural simulation: proxy measure)
PROCESS EVALUATION	
Program Logic model or Proceed-Precede model	
OUTCOME EVALUATION	
Patient health outcomes*	<p><u>Quantitative</u></p> <ul style="list-style-type: none"> • PROMIS : http://www.nihpromis.org/?AspxAutoDetectCookieSupport=1 • AHRQ : http://www.qualityindicators.ahrq.gov/ • Field J. Care Response⁸: Free, pragmatic system to help practices gather and report clinical outcome and patient satisfaction information https://www.care-response.com/CareResponse/home.aspx • Any outcome measure relevant to the content area (e.g. Oswestry, NDI, VAS scores...) • Patient Satisfaction Questionnaire (from RAND Health) <p><u>Qualitative</u></p> <ul style="list-style-type: none"> • Semi-structured interviews

Framework adapted from Edith Strauss Rehabilitation Research Project (in Knowledge Translation). School of Physical and Occupational Therapy, McGill University

***Ideally these outcome measures should be used at baseline and at post-intervention, but can also be administered during the intervention**

References and resources:

1. Green, LA, Gorenflo, DW, Wyszewianski, L. Validating an instrument for selecting interventions to change physician practice patterns: A Michigan Consortium for Family Practice Research study. *Journal of Family Practice*. 2002 Nov; 51(11): 938-942.
 2. Mutsaers JH1, Pool-Goudzwaard AL2, Ostelo RW3, Peters R4, Koes BW5, Verhagen AP6. The psychometric properties of the PABS-PT in neck pain patients: A validation study. *Man Ther*. 2014 Jan 18. pii: S1356-689X(13)00216-6.
 3. Mutsaers JH1, Peters R, Pool-Goudzwaard AL, Koes BW, Verhagen AP. Psychometric properties of the Pain Attitudes and Beliefs Scale for Physiotherapists: a systematic review. *Man Ther*. 2012 Jun;17(3):213-8. doi: 10.1016/j.math.2011.12.010. Epub 2012 Jan 23.
 4. Ostelo RW, Stomp-van den Berg SG, Vlaeyen JW, Wolters PM, de Vet HC. Health care provider's attitudes and beliefs towards chronic low back pain: the development of a questionnaire. *Man Ther* 2003;8:214e22.
 5. Salbach, N. M. and Jaglal, S. B. (2011), Creation and validation of the evidence-based practice confidence scale for health care professionals. *Journal of Evaluation in Clinical Practice*, 17: 794–800. doi: 10.1111/j.1365-2753.2010.01478.x
Evidence based practice attitude scale (EBPS)
 - Aarons GA, Cafri G, Lugo L, Sawitzky A. Expanding the domains of attitudes towards evidence-based practice: the evidence based practice attitude scale-50. *Adm Policy Ment Health*. 2012 Sep;39(5):331-40. doi: 10.1007/s10488-010-0302-3.
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Evidence-Based Practice Attitude and Utilization SurvEy (EBASE)
 - Leach MJ, Gillham D. Evaluation of the Evidence-Based practice Attitude and utilization SurvEy for complementary and alternative medicine practitioners. *J Eval Clin Pract*. 2008; 14(5):792-8.
Theoretical Domain Framework (TDF)
- Theoretical Domains Framework for behaviour change research: <http://www.implementationscience.com/series/TDF>
- Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A: 'Psychological Theory' Group. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality & Safety in Health Care* 2005, 14:26 - 33.
 - Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science*. 2012;7(1):37. PubMed PMID: doi:10.1186/1748-5908-7-37.
 - Huijig JM, Gebhardt WA, Dusseldorp E, Verheijden MW, van der Zouwe N, Middelkoop BJ, Crone MR. Measuring determinants of implementation behavior: psychometric properties of a questionnaire based on the theoretical domains framework. *Implement Sci*. 2014 Mar 19;9:33. doi: 10.1186/1748-5908-9-33.
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Communication Skill
 - Baig LA, Violato C, Crutcher RA. Assessing clinical communication skills in physicians: are the skills context specific or generalizable. *BMC Medical Education* 2009, 9:22
7. Menon A, Cafaro T, Loncaric D, Moore J, Vivona A, Wynands E, Korner-Bitensky N. Creation and validation of the PERFECT: a critical incident tool for evaluating change in the practices of health professionals. *Journal of Evaluation in Clinical Practice*. 2010 Dec; 16(6) 1170-1175. Refer to StrokEngine Assessment for more details on PERFECT: www.strokengine.ca
- Reviews:**
- Chaudoir, S. Dugan AG. Barr CHI. Dissemination Measurement Compendium: A Systematic review provider, patient, and implementation. Review of structural, organizational innovation level measures. Connecticut Institute for Clinical and Translational Science. *Implementation Science* 2013, 8:22 <http://www.implementationscience.com/content/8/1/22>
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- Organizational**
- Context Assessment Index (CAI). McCormack B, McCarthy G, Wright J, Slater P, Coffey A. Development and testing of the Context Assessment Index (CAI). *Worldviews Evid Based Nurs* 2009;6(1):27-35. doi: 10.1111/j.1741-6787.2008.00130.x. Epub 2009 Jan 16.
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- Stage of Implementation Completion (SIC): Chamberlain P, Brown H, Saldana L. Observational measure of implementation progress in community based settings: The Stages of implementation completion (SIC). *Implementations Sci* 2011, 6:116.
<http://www.implementationscience.com/content/pdf/1748-5908-6-116.pdf>
- Damschroder L, Aron D, Keith R, Kirsh S, Alexander J, Lowery J. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Sci* 2009;4:50. PubMed PMID: doi:10.1186/1748-5908-4-50.
- Patient outcomes**
- PROMIS : <http://www.nihpromis.org/?AspxAutoDetectCookieSupport=1>
 - AHRQ : <http://www.qualityindicators.ahrq.gov/>
 - Field J. Care Response: <https://www.care-response.com/CareResponse/home.aspx>

Appendix

Components of a Review Proposal (<http://www.york.ac.uk/>)

1. Background
2. Review questions
3. Methods
 - a. Search strategy including search terms and resources to be searched
 - b. Study selection criteria and procedures
 - c. Study quality assessment checklists and procedures
 - d. Data extraction strategy
 - e. Synthesis of the extracted evidence
4. Ethical considerations
5. Logistics
 - a. Distribution of responsibilities
 - b. Project timetable
 - c. Budget
6. References
7. Appendices

Guide Outline of a Research Project Proposal

1. Study title, principle collaborators and institutions
2. Abstract
3. Background
4. Aims and objectives
5. Methods
 - a. Study description
 - i. Study design
 - ii. Study site
 - iii. Study population
 - iv. Proposed intervention (if an intervention study)
 - v. Main exposures and/or confounders and/or outcomes to be measured
 - b. Selection of study population
 - i. Inclusion criteria
 - ii. Exclusion criteria
 - iii. Sampling
 - iv. Randomisation (if a randomised trial)
 - c. Study procedures
 - i. Procedures at enrolment
 - ii. Follow-up (if a cohort study or trial)
 - iii. Measurement of exposures and confounders
 - iv. Measurement of outcomes
 - d. Sample size

- e. Data management
- f. Proposed analysis
- 2. Ethical considerations
 - a. Confidentiality
 - b. Informed consent
 - c. Ethical approval
- 3. Logistics
 - a. Distribution of responsibilities
 - b. Timetable
 - c. Budget
- 4. References

Guide of items for inclusion in a qualitative research protocol

- 1. Study title, principle collaborators and institutions
- 2. Abstract
- 3. Background
 - What is already known
 - How will this work contribute to knowledge
- 4. Aims and objectives
- 5. Methods
 - Qualitative approach/tradition
 - Sampling
 - Data collection
 - Data management
 - Proposed analysis
- 6. Results and Conclusions
- 7. Ethical considerations
 - Confidentiality
 - Informed consent
 - Ethical approval
- 8. Logistics
- 9. References