Cochrane Upper Gastrointestinal and Pancreatic Diseases Group

Guidance for the completion of your Cochrane **Protocol**

Revised January 2014

INTRODUCTION

This guide has been created by the UGPD group to assist authors with a protocol title registered with the UGPD group. As such, we have included guidance particular to our authors which may or may not be applicable in other Cochrane groups. The guidance is presented in the order in which you will encounter sections in RevMan, the software used to author Cochrane protocols.

We have included details of the Methodological Expectations of Cochrane Intervention Reviews (MECIR) standards particular to each section in text boxes on the right hand side. The MECIR project aims to specify methodological conduct and reporting expectations for Cochrane Protocols, Reviews, and updates of reviews on the effects of interventions, and to ensure that these methodological expectations are supported and implemented across The Cochrane Collaboration. Standards which are mandatory are framed in red (such as the one under "Objectives"), while standards which are recommended are framed in blue (as under "Types of Participants"), and are noted by their number followed by "c" to signify that they relate to the conduct standards, or "r" for reporting standards. Please ensure you address all mandatory standards in your review. Please see http://www.editorial-unit.cochrane.org/mecir for further details on the MECIR standards.

Please ensure you address all mandatory standards in your protocol. Please see http://www.editorial-unit.cochrane.org/mecir for further details on the MECIR standards.

PRIOR TO STARTING YOUR PROTOCOL

Prior to starting your protocol, the following fields should have been completed during the title registration process. If they haven't been completed, or if revisions are necessary, please contact the UGPD group Managing Editor.

TITLE

1r The review title should follow the standard template for a Cochrane title as detailed in Table 4.2.a of the Cochrane handbook.

The title should succinctly state the focus of the review. It should make clear the intervention(s) reviewed and the problem at which the intervention is directed. Someone reading the title on its own should be able to decide quickly whether the review addresses a question of interest. At its most basic, a title should take the structure 'Intervention for condition'. Other structures are included in the Style Guidelines for Cochrane reviews (http://www.liv.ac.uk/lstm/ehcap/CSR/home.html). Specific outcomes should be mentioned only rarely within the title. If so, this should usually be done as a subtitle separated by a colon from the main title. Do not start your title with "A systematic review of the effectiveness of …" – all Cochrane reviews are!

AUTHORS

2r All authors and their affiliations should be listed as detailed in section 4.2.2 of the Cochrane handbook.

This should be a list of co-authors on the review. When deciding who should go in the byline for Cochrane reviews, it is important to distinguish individuals who have made a substantial contribution to the review (and who should be listed) and those who have made other contributions, which should be noted in the Acknowledgements section. Authorship should be based on substantial contributions to all of the following three steps, based on conception and design of study, or analysis and interpretation of data drafting the review or revising it critically for important intellectual content final approval of the version to be published. Brief contact details of co-authors may be published within the completed protocol or review, so authors should ensure that these fields are completed and up-to-date in RevMan. The fields that must be completed are the First name(s) and Last name, Organisation and Country. If a co-author does not have a publishable address, but should still appear in the byline for the citation, then the Organisation and Country should be those of the Review Group (for example, 'Smith J. c/o Cochrane Pregnancy and Childbirth Group, UK').

The format for the byline of the protocol is Last-name Initial(s), without prefix (such as Dr) or internal punctuation but with a comma between names (for example, 'Jepson RG, Mihaljevic L, Craig JC'). The list of authors for citations can be the name of

an individual, several individuals or a collaborative group (for example, 'Early Breast Cancer Trialists' Collaborative Group'). Ideally, the order of authors should relate to their relative contributions to the review. The person who contributed most should be listed first.

CONTACT AUTHOR

This should provide the contact details for the person to whom correspondence about the review should be addressed, and who has agreed to take responsibility for maintaining and developing the review. This usually is the person who takes responsibility for developing and organizing the review team, communicates with the editorial base, ensures that the review is prepared within agreed timescales, submits it to the editorial base, communicates feedback to co-authors and ensures that the updates are prepared.

The contact author need not be the first listed author, and the choice of contact author will not affect the citation for the review. If the contact author no longer wishes to be responsible for a published review and another member of the review team does not wish to take responsibility for it, then the Managing Editor (ME) should be listed as the contact author, and the former contact author listed as a co-author. The ME need not be listed as a co-author.

PROPERTIES

The properties about your protocol are accessible from within Archie. To access the properties, log in to Archie (archie.cochrane.org), and choose your protocol title. From the "file" menu, choose "properties". Some of the items on the "general" and "advanced" tabs are described below.

REVMAN ID

A unique 18-digit number is assigned to each review and is used by Archie to match up version of protocols under one title.

DOI

Digital object identifiers (DOIs) are assigned by the publisher of the Cochrane Library, and will be assigned to your protocol once published.

REVIEW NO

The UGPD group assigns a unique review number to each review title. We kindly ask that you do not edit this number as it is used for our internal tracking.

VERSION NO

One version of each review must be marked as the primary version and this is the one that should be submitted for publication in the CDSR.

STATUS

This specifies what stage the review is active, withdrawn or inactive. For protocols in development the status should be "active".

STAGE

This specifies what stage the review is at: title, protocol or full review. Titles are only used internally, within Collaborative Review Groups, and are not included in the Cochrane Database of Systematic Reviews (CDSR). For protocols in development the stage should be "Protocol".

PROTOCOL INFORMATION

CO-AUTHORS

The order of the authors may be altered by expanding the "Protocol information" and "authors" sections in the left hand panel in RevMan. Click on the author name to be moved, highlighting it, then using your secondary mouse button, choose "move up" or "move down" to reposition. Changes to the details of an author's record can only be done by the author logging into Archie, or by the Cochrane Review Group.

DATES

Note that the date fields are not all published in the CDSR. They should all be completed by the author (reviewer) or Collaborative Review Group (CRG) in RevMan.

ASSESSED AS UP-TO-DATE

This date does not apply to protocols and should be left blank.

DATE OF SEARCH

This date does not apply to protocols and should be left blank.

NEXT STAGE EXPECTED

This date should be completed for protocols so that users of the CDSR will know when they can expect the completed review to be available. Normally this date is within one year of the submission of the protocol.

PROTOCOL FIRST PUBLISHED

This date will automatically be included when the protocol is published in the Cochrane library.

REVIEW FIRST PUBLISHED

This does not apply to protocols and should be left blank.

LAST CITATION ISSUE

This date will automatically be included when the protocol is published in the Cochrane library.

WHAT'S NEW

This does not apply to protocols and should be left blank.

HISTORY

This does not apply to protocols and should be left blank.

MAIN TEXT

Cochrane reviews should be written so that they are easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be helpful, and perhaps even essential. However, too much explanation can detract from the readability of a review. Simplicity and clarity are also vital to readability.

The readability of Cochrane reviews should be comparable to that of a well-written article in a general medical journal.

The text of a Cochrane review contains a number of fixed headings that are embedded in RevMan. Subheadings may be added by the author at any point. Certain specific headings are recommended for use by all authors, but are not mandatory and should be avoided if they make individual sections needlessly short. Wording for further subheadings that may or may not be relevant to a particular review is also provided.

ABSTRACT

This does not apply to protocols and should be left blank.

PLAIN LANGUAGE SUMMARY

This does not apply to protocols and should be left blank.

BACKGROUND

Well-formulated review questions usually do not appear out of thin air. They occur in the context of an already formed body of knowledge. This context should be addressed in the background section of the review. This background helps set the rationale for the review, and should explain why the questions being asked are important. It should be presented in a fashion that is understandable to the users of the health care under investigation, and should be concise (generally around one page when printed).

DESCRIPTION OF THE CONDITION

The review should begin with a brief description of the condition being addressed and its significance. It may include information about the biology, diagnosis, prognosis and public health importance (including prevalence or incidence worldwide, if possible). All information should be backed with references. Information on linking the references into the text can be found in RevMan help and this should be done before submitting your protocol to the editorial base.

DESCRIPTION OF THE INTERVENTION

A description of the experimental intervention(s) should place it in the context of any standard, or alternative interventions. It should be made clear what role the comparator intervention(s) have in standard practice.

HOW THE INTERVENTION MIGHT WORK

Systematic reviews gather evidence to assess whether the expected effect of an intervention does indeed occur. This section might describe the theoretical reasoning why the interventions under review might have an impact on potential recipients, for example, by relating a drug intervention to the biology of the condition.

Authors may refer to a body of empirical evidence such as similar interventions having an impact, or identical interventions having an impact on other populations. Authors may also refer to a body of literature that justifies the possibility of effectiveness. Although every review, just like every intervention, is based on a theory, this may not be explicit or well explored. Controversy remains about whether or not theory makes a difference to intervention effectiveness, but as Oakley (1999) points out “the importance or unimportance of theory is unlikely to emerge unless review activity is structured to cross problem/outcome areas, and allow for the classification of interventions according to their theoretical base.”

WHY IT IS IMPORTANT TO DO THIS REVIEW

The background helps set the rationale for the review, and should explain why the questions being asked are important. It might also mention why this review was undertaken and how it might relate to a wider review of a general problem.

OBJECTIVES

This should begin with a precise statement of the primary aim of the review, including the intervention(s) reviewed and the targeted problem. This might be followed by a series of specific objectives relating to different participant groups, different comparisons of interventions or different outcome measures.

1c The review question and outcomes should address issues that are important to stakeholders
2c Define in advance the objectives (participants, interventions, comparators and outcomes)

METHODS

The Methods section in a protocol should be written in the **future tense**. Because Cochrane reviews are updated as new evidence accumulates, methods outlined in the protocol should generally anticipate a sufficiently large number of studies to address the review's objectives (even if it is known this is not the case).

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

The criteria used to select studies for inclusion in the review must be clearly stated.

TYPES OF STUDIES

Eligible study designs should be stated here, along with any thresholds for inclusion based on the conduct or quality of the studies. For example, 'All randomized controlled comparisons' or 'All randomized controlled trials with blind assessment of outcome'. Exclusion of particular types of randomized studies (for example, cross-over trials) should be justified.

9c Define in advance the eligibility criteria for study designs
10c Include randomized trials as eligible for inclusion in the review, if they are feasible for the interventions and outcomes of interest
11c Justify the choice of eligible study designs
12c Include studies irrespective of their publication status, unless explicitly justified
13c Justify any changes to eligibility criteria or outcomes studied

TYPES OF PARTICIPANTS

The diseases or conditions of interest should be described here, including any restrictions on diagnoses, age groups and settings. Subgroup analyses should not be listed here.

5c Define in advance the eligibility criteria for participants in the studies

4c Consider in advance whether issues of equity and relevance of evidence to specific populations are important to the review
6c Define in advance how studies that include only a subset of relevant participants will be handled

TYPES OF INTERVENTIONS

Experimental and control interventions should be defined here, making it clear which comparisons are of interest. Restrictions on dose, frequency, intensity or duration should be stated. Subgroup analyses should not be listed here.

7c Define in advance the eligible interventions and comparators

TYPES OF OUTCOME MEASURES

Note that outcome measures do not always form part of the criteria for including studies in a review. If they do not, then this should be made clear. Outcome measures of interest should be listed in this section whether or not they form part of the inclusion criteria.

3c Consider any important potential adverse effects are addressed
8c Clarify in advance whether outcomes listed under 'Criteria for considering studies for this review' are used as criteria for including studies
14c Define in advance which outcomes are primary and secondary outcomes

Primary outcomes should normally reflect at least one potential benefit and at least one potential area of harm, and should be as few as possible. Secondary outcomes should include all other non-primary outcomes. Additional subheadings for; adverse outcomes, economic data, and timing of outcome assessment may be added if appropriate.

15c Keep the total number of outcomes selected for inclusion as small as possible
16c Pre-define what are acceptable outcome measures
17c Pre-define how outcome measures will be selected when there are several possible measures
18c Pre-define the timing of outcome measurement

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

Before starting to develop this section, authors should contact the editorial base for guidance as your search strategy will be developed by our Trials Search Co-ordinator in conjunction with the authors.

ELECTRONIC SEARCHES

The bibliographic databases to be searched, the dates and periods to be searched and any constraints, such as language should be stated. The full search strategies for each database should be in an appendix. If a CRG has developed a Specialized Register of studies and this is searched for the review, a standard description of this register can be referred to but information should be included on when and how the Specialized Register was most recently searched for the current version of the review and the search terms used should be listed.

19c Plan in advance the methods to be used for identifying studies
24c Search key databases (CENTRAL, Medline, etc)
26c Search for different types of evidence (e.g. economic) where appropriate
32c Structure search strategies around the main concepts of the review using elements from PICO and study design
33c Identify appropriate controlled vocabulary (e.g. MeSH, Emtree)
35c Justify the use of any restrictions in the search strategy on publication date or publication format
36c Document the search process so it can be reported correctly in the review
37c Rerun or update searches for all relevant databases within 12 months before publication of the review/review update

25c Search appropriate nation, regional and subject specific bibliographic databases
34c Use specially designed and tested search filters where appropriate
38c Incorporate fully any studies identified in the rerun or update of the search within 12 months before publication of the review/review update

Authors are welcome to use the following text for this section, adding additional resources when appropriate:

> We will conduct a comprehensive literature search to identify all published and unpublished randomized controlled trials with no language restriction. We will search the following electronic databases to identify potential studies:
>
> Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library) (Appendix 1);
> MEDLINE 1966 to present (Appendix 2);
> EMBASE 1980 to present (Appendix 3); and
> LILACS 1982 to present (Appendix 4).

SEARCHING OTHER SOURCES

List grey literature sources, such as reports and conference proceedings to be searched. If journals are to be hand searched for the review, this should be noted but hand searching done by the authors to help build the Specialized Register of the CRG should not be listed. List people (for example, trialists, experts) and/or organizations will be contacted. List any other sources, which may include, for example, reference lists, the World Wide Web or personal collections of articles. The following optional headings may be used as subheadings: Grey literature, Handsearching, Reference lists, and Correspondence.

27c Search trials registers and repositories of results where relevant to topic (e.g. ClinicalTrials.gov, ICTRP etc)
30c Check reference lists in included studies and any relevant systematic reviews

28c Search relevant grey literature sources such as report, dissertations, theses etc.
29c Search within previous reviews on the same topic
31c Contact relevant individuals and organizations for information about unpublished or ongoing studies

DATA COLLECTION AND ANALYSIS

This should describe the methods you plan to use for data collection and analysis and should again be written in the future tense.

SELECTION OF STUDIES

The method used to apply the selection criteria. Whether they are applied independently by more than one author should be stated, along with how any disagreements will be resolved.

39c Use at least two people working independently to determine whether each study meets the eligibility criteria
40c Include studies irrespective of whether measure outcomes data are reported in a 'usable' way
41c Document the selection process in sufficient detail to complete a PRISMA flow chart and a table of 'Characteristics of excluded studies'
42c Collate multiple reports of the same study so that each study rather than each report is the unit of interest in the review

DATA EXTRACTION AND MANAGEMENT

The method used to extract or obtain data from published reports or from the trialists (for example, using a data extraction/data collection form). Whether data are extracted independently by more than one author should be stated, along with how any disagreements will be resolved. If relevant, methods for processing data in preparation for analysis should be described.

43c Use a data collection form, which has been piloted
44c Collect characteristics of the included studies to populate a table of 'Characteristics of included studies'
45c Use at least two people to independently extract study characteristics
46c Use at least two people to independently extract outcome data
47c Collect and use the most detailed numerical data that might facilitate similar analyses of included studies
50c If a study is included with more than two intervention arms, include in the review only intervention and control groups that meet the eligibility criteria.
50c Compare the magnitude and direction of effects reported by studies with how they are presented in the review

48c Examine any relevant retractions or errata
49c Seek key unpublished information that is missing from reports of included studies

ASSESSMENT OF METHODOLOGICAL QUALITY OF INCLUDED STUDIES

The method used to assess methodological quality. Whether methods are applied independently by more than one author should be stated, along with how any disagreements will be resolved. The tool(s) used should be described or referenced, with an indication of how the results are incorporated into the interpretation of the results.

20c Plan in advance the methods to be used for assessing risk of bias
52c Assess the risk of bias for each included study
53c Use at least two people to independently apply the risk of bias tool
54c Justify judgements of risk of bias in the Risk of Bias tables
61c Use the Cochrane tool as the primary assessment of bias

55c Collect the source of information for each risk of bias judgement
56c Consider separately the risks of bias due to lack of blinding for i) participants and study personnel, and ii) outcome assessment
57c Consider blinding separately for different key outcomes
58c Consider the impact of missing data separately for different key outcomes
59c Summarize the risk of bias for each key outcome
60c Address risk of bias in the synthesis

MEASURES OF TREATMENT EFFECT

The effect measures of choice should be stated. For example, odds ratio (OR), risk ratio (RR) or risk difference (RD) for dichotomous data; difference in means (MD) or standardized difference in means (SMD) for continuous data. Alternatively, optional headings specific to the type of data may be used, such as: Dichotomous data, Continuous data, and Time-to-event data.

UNIT OF ANALYSIS ISSUES

Special issues in the analysis of studies with non-standard designs, such as cross-over trials, cluster randomized trials and non-randomized studies, should be addressed (see The Cochrane Reviewers Handbook Section 8.3. Study designs and identifying the unit of analysis). Alternatively, optional (level 2) headings specific to the types of studies may be used, such as: Studies with multiple treatment groups, Cross-over trials, Cluster randomized trials.

DEALING WITH MISSING DATA

Strategies for dealing with missing data should be described. This will principally include missing participants due to drop-out (whether an intention-to-treat analysis will be conducted), and missing statistics (such as standard deviations or correlation coefficients).

ASSESSMENT OF HETEROGENEITY

Approaches to addressing clinical heterogeneity should be described, along with how the authors will determine whether a meta-analysis is considered appropriate. Methods for identifying statistical heterogeneity should be stated (for example, visually, using a Chi^2 test, or using I^2 statistic). See the Cochrane Reviewers Handbook Section 8.7 on Heterogeneity.

ASSESSMENT OF REPORTING BIASES

This section should include a description of how publication bias, and other reporting biases are addressed (for example, funnel plots, statistical tests, imputation). Authors should remember that asymmetric funnel plots are not necessarily caused by publication bias (and that publication bias does not necessarily cause asymmetry in a funnel plot). See the Cochrane Reviewers Handbook Section 8.11.1 on Publication bias and funnel plots.

DATA SYNTHESIS (META-ANALYSIS)

The choice of meta-analysis method should be stated, including whether a fixed effect or a random effects model is used. If meta-analyses are not undertaken, systematic approaches to synthesizing the findings of multiple studies should be described.

21c Plan in advance the methods to be used to synthesize the results
62c If combining studies with different scales, ensure higher scores for continuous outcomes have the same meaning
63c Undertake or display a meta-analysis only if participants, interventions, comparisons and outcomes are sufficiently similar
64c Assess the presence and extent of between-study variation
67c If multi-arm studies are included, analyse multiple intervention groups in an appropriate way that avoids double-counting or omission of participants
71c Consider the impact on the analysis of clustering, matching or other non-standard design features
73c Interpret a statistically non-significant P value (> 0.05) as a finding of uncertainty unless confidence intervals are sufficiently narrow to rule out an important magnitude of effect

65c Consider the implications of missing outcome data from individual participants
66c Consider the possibility and implications of skewed data when analyzing continuous outcomes
74c Consider the potential impact of reporting biases on the results of the re review or meta-analyses

SUBGROUP ANALYSIS AND INVESTIGATION OF HETEROGENEITY

All planned subgroup analyses should be listed (or independent variables for meta-regression). Any other methods for investigating heterogeneity of effects should be described.

22c Pre-define potential effect modifiers
68c If subgroup analyses are to be compared, and there are sufficient studies, use a formal statistical test
69c If subgroup analyses are conducted, follow the subgroup analysis plan specified in the protocol
70c Take into account any statistical heterogeneity when interpreting the results

SENSITIVITY ANALYSIS

This should describe analyses aimed at determining whether conclusions are robust to decisions made during the review process, such as inclusion/exclusion of particular studies from a meta-analysis, imputing missing data or choice of a method for analysis.

72c Use sensitivity analyses to assess the robustness of results

SUMMARY OF FINDINGS

Methods for 'Summary of findings' tables should be pre-defined, particularly with regard to choice of outcomes, to guard against selective presentation of results in the review. The table should include the essential outcomes for decision making (typically up to seven), which should generally not include surrogate or interim outcomes.
These outcomes should not be chosen on the basis of any anticipated or observed magnitude of effect, or because they are likely to have been addressed in the studies to be reviewed.

76c Use GRADE to assess the quality of the body of evidence for each outcome
77c Justify and document all assessments of the quality of the body of evidence

23c Plan in advance the methods to be used for summarizing the findings of the review
75c Include a 'Summary of Findings' table

RESULTS

This does not apply to protocols and should be left blank.

DISCUSSION

This does not apply to protocols and should be left blank.

AUTHORS' CONCLUSIONS

This does not apply to protocols and should be left blank.

78c Base conclusions on findings from the synthesis (quantitative or narrative) of studies included in the review
79c Avoid providing recommendations for practice

80c Structure the implications for research to address the nature of evidence required

ACKNOWLEDGEMENTS

This section should be used to acknowledge any individuals or organizations who are not listed among the authors. This would include any previous authors of the Cochrane review and might include the peer referees or contributions of the editorial team of the CRG. Permission should be obtained from persons acknowledged.

CONTRIBUTIONS OF AUTHORS

The names and contribution of the present co-authors should be described in this section. One author, usually the contact author, should be identified as the guarantor of the protocol. All authors should discuss and agree on their respective descriptions of contribution before the protocol is submitted for publication in the CDSR.

The following potential contributions have been adapted from Yank 1999. This section should describe what people did, rather than attempt to identify which of these categories someone's contribution falls within. Ideally, the contributors should describe their contribution in their own words:

1. Conceiving the protocol
2. Designing the protocol
3. Coordinating the protocol
4. Designing search strategies
5. Writing the protocol
6. Providing general advice on the protocol
7. Securing funding for the protocol
8. Performing previous work that was the foundation of the current study

DECLARATIONS OF INTEREST

Authors should report any conflict of interest that might be perceived by others as being capable of influencing their judgments, including personal, political, academic and other possible conflicts, as well as financial conflicts. Authors must state if they have been involved in a study included in the review. Details of the Collaboration's policy on conflicts of interest appear in The Cochrane Reviewers Handbook 2.6 Conflict of interest and commercial sponsorship. Financial conflicts of interest cause the most concern, and should be avoided, but must be reported if there are any. Any secondary interest (such as personal conflicts) that might unduly influence judgments made in a review (concerning, for example, the inclusion or exclusion of studies, assessments of the validity of included studies or the interpretation of results) should be reported. If there are no conflicts of interest, this should be stated explicitly, for example, by writing 'None known'.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This does not apply to protocols and should be left blank.

PUBLISHED NOTES

These will be published in the CDSR. They may include: editorial notes and comments from the CRG, for example where issues highlighted by editors or referees are believed worthy of publication alongside the review; a summary of previous changes to the review. Changes since the previous published version must be stated under 'What's new'.

The published notes must be completed for all withdrawn publications to give the reason for withdrawal. Only the cover sheet and published notes are published for withdrawn protocols and reviews.

TABLES

Additional tables may be included in protocols if required. They should be references in the text by clicking "Insert link" from your secondary mouse button within the RevMan file.

STUDIES AND REFERENCES

At the protocol stage, you should only have references in the Additional References section of RevMan. The reference ID should be in the format "Surname Year". References should be referenced in the text by clicking "Insert link" from your secondary mouse button within the RevMan file.

DATA AND ANALYSES

This does not apply to protocols and should be left blank.

FIGURES

Figures may be included in protocols if required. They should be referenced in the text by clicking "Insert link" from your secondary mouse button within the RevMan file.

SOURCES OF SUPPORT

Authors should give details of grants that supported the review and other forms of support, such as support from their university or institution in the form of a salary. Sources of support are divided into 'internal' (provided by the institutions at which the review was produced) and 'external' (provided by other institutions or funding agencies).

FEEDBACK

This does not apply to protocols and should be left blank.

APPENDICES

An appendix should be created for each search strategy (e.g. titled "CENTRAL search strategy")

TOOLS

Before submitting your protocol for editorial consideration and publication, please use the following tools.

SPELLING

Please check the spelling throughout the protocol. A spell check function is available in RevMan, under the "tools" menu, listed as "Check Spelling".

VALIDATION

Running a validation report in RevMan will list if there are any errors or warnings in the protocol to be addressed. The report may be accessed by the "File" menu, "Reports", "Validation report". Please correct all errors. Protocols with errors are unable to be published. Please contact the UGPD group if you have any difficulty in resolving errors or warnings.

HOW TO SUBMIT

You submit ("check in") the protocol online using Archie and /or RevMan. When checking in, after typing a Version Description, click "next", so that you are shown the tick box option for "Submit for editorial approval". Check this box. Once you have checked in a protocol and ticked this box, the editorial office will be notified and the protocol will be inaccessible by authors until approved for publication or unlocked by the editorial office.

GETTING HELP

If you have any questions on preparing your protocol that are not answered by this document, the User Guide (found in the "Help" section of RevMan) or by the Cochrane Handbook (http://www.cochrane-handbook.org/) please contact the editorial base at mailto:dearnes@mcmaster.ca.