

Formatting Guide for Clinical Research Protocols

On first review, we are very flexible about the format of the manuscript in order to facilitate reviews of manuscripts that have been prepared without our journal in mind or which have been previously submitted and declined elsewhere. If a manuscript has standard or sensible structure and meets ethical standards, we will consider it.

However, if you are preparing the manuscript specifically for CJKHD, please follow these guidelines as you develop your work.

If you receive a decision of major or minor revisions, one of the requirements at that time is to comply with mandatory formatting requirements.

Mandatory formatting requirements

- **Compliance with limitation for word count**
 - **Strict limit of 5,000 words**
- **Non-declarative title that includes the words ‘clinical research protocol’**
- **Structured abstract using headings below, no more than 4096 characters including spaces (about 650 words)**
- **Structured manuscript using headings below**
- **Ethical considerations (see end of document)**

Overview

This publication type includes any planned work that is in progress, whether clinical, translational, and population research, including protocols for systematic reviews and meta-analyses.

We wish to encourage the publication of protocols that are based on grant submissions describing work that is now in progress (usually because the grant was funded). Grant submissions are usually longer than the 5,000 word limit and include information that is of limited interest to readers. The following modifications account for these differences.

If you are preparing your manuscript based on such a grant, move all figures and tables to the end of the manuscript, as is usual in a manuscript submission. Remove details of the team and its suitability to perform the work, and do not include budget, CVs, or appendices.

Review the tone of writing throughout and ensure it is appropriate for publication. Review the expectations that your work has from your readers and adjust based on the readership of CJKHD.

If you are submitting a protocol that is revised from a funded grant, please also submit the feedback from the peer review committee, including the scientific officer’s notes, along with a point by point response, and show where the feedback has led to changes in the protocol as implemented and submitted for publication, or explain why you did not change as suggested. This will allow us to expedite review of your manuscript.

Title Page

The title page should:

- Present a title that includes the words ‘clinical research protocol’ e.g.:
 - "A versus B in the treatment of C: a clinical research protocol", "X as a risk factor for Y: a clinical research protocol"
 - Because the scientific process is rarely unequivocal, we do not favor declarative titles (e.g. “A reduces Y in the treatment of C”). However, if you feel your work is best served by a declarative title, you may use one and justify it in the cover letter.
- List the full names, institutional addresses and email addresses for all authors
 - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the “Acknowledgements” section in accordance with the instructions below
- Indicate the corresponding author

Abstract

The Abstract should not exceed 4096 characters including spaces (about 650 words), and will usually be less than 500 words. (PubMed truncates abstracts at 4096 characters.) Please minimize the use of abbreviations and do not cite references in the abstract.

Abstracts for study protocols in clinical research should include the following separate sections:

- Background
- Objective
- Design
- Setting
- Patients
- Measurements
- Methods
- Results (may be omitted if no preliminary results)
- Limitations
- Conclusions
- Trial registration: If your article is a systematic review or reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be in stated in this section.

The abstract will be translated into French by CJKHD staff once the English is finalised.

Keywords

Five keywords representing the main content of the article.

Introduction

The background section should explain the background to the study, its aims, a summary of the existing

literature and why this study is necessary and how it contributes to the field.

If you are basing your report on a grant application, the background can be argued as a series of evidence-based assertions that build the argument for the need for a study now, explanation of technical details, and justification of specific methods compared with others, etc, or whatever flow of argument you made in the introduction to your grant. Edit for tone, and to take into account the CJKHD readership, and remove those sections which describe your team and its suitability to conduct the work.

Whether you are starting with a grant, or writing specifically for the journal, use the background to cover the following issues:

- Why is the problem important?
- What is currently known?
- Why is this work the appropriate next step?

Methods

The methods section may also be retained in the format of methods written for a grant. Edit for tone and readership. Remove details of your team and its suitability to conduct the work. Limitations, potential pitfalls, and mitigating strategies can be retained.

Whether you are starting with a grant, or writing specifically for the journal, use the background to cover the following issues:

- The design and setting of the study
- The characteristics of participants
- A clear description of all processes, laboratory methods, sampling strategies, recruitment procedures, randomization procedures, variable definitions, data instruments and their validity, interventions, outcomes definitions, and comparisons. Generic drug names should generally be used: when proprietary brands are used, give the generic name first and include the brand names in parentheses.
- The type of statistical analysis to be used, including a hierarchy of outcomes (primary, secondary), a power calculation, and the software used and to be used (including version, manufacturer, city of origin).

Results

Validation of methodology, progress to date and preliminary data should be included. If these are integrated into the methods section, omit the results section.

Discussion

Omit this section if all the background issues, limitations, potential pitfalls and mitigating strategies have already been discussed, and the place of the new work in the context of existing literature is clear.

If these issues are not covered elsewhere, we provide these suggested structures:

1. Statement of principal outcomes and analysis plan
2. Strengths and weaknesses of the proposed study
3. Strengths and weaknesses in relation to other studies
4. Meaning of the study: possible implications for clinicians or policymakers
5. Unanswered questions and future research directions

(Source: Docherty M, Smith R. The case for structuring the discussion of scientific papers : Much the same as that for structuring abstracts . BMJ : British Medical Journal. 1999;318(7193):1224-1225.

Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1115625/>)

1. Provide a brief synopsis of planned key findings, with particular emphasis on how the findings add to the body of pertinent knowledge.
2. Contextualize the study with relevant findings from other published work. Briefly state literature search sources and methods (e.g., English-language MEDLINE search to Jan 2007) that identified previous pertinent work. Use tables and figures to help summarize previous work when possible.
3. Discuss the limitations of the present study and any methods used to minimize or compensate for those limitations.
4. Conclude with a brief section that summarizes in a straightforward and circumspect manner the possible clinical implications of the work.

(Source: Annals of Internal Medicine. Information for Authors.)

Conclusions

This should restate, in one to three sentences, the importance and design of the study. Present a balanced view and do not speculate on anticipated results.

Ethical considerations

This can be a separate section or integrated into methods.

- Clinical trials should be registered and the number included in the manuscript
- All studies that involve human investigation need to state in the manuscript that they have REB approval