

Guide for Submission of Specialized Registers to the Cochrane Central Register of Controlled Trials (CENTRAL)

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This document will be updated as necessary. Review Group Coordinators and Trials Search Coordinators are invited to send in comments that could be incorporated into future versions.

Who is this document for?

This Guide is for the person within a Collaborative Review Group (CRG) or Field/Network who is responsible for submission of that entity's specialized register to the Cochrane Central Register of Controlled Trials (CENTRAL). This is usually the Review Group Coordinator (RGC) or Trials Search Coordinator (TSC). For brevity, the relevant person is referred to as "the RGC/TSC" throughout this document.

1. When to submit

Specialized registers may be submitted at any time; however, it is ideal to submit specialized registers four times per year, so that the most up to date register is always included in each quarterly issue of *The Cochrane Library* and CENTRAL. Specialized registers must be received by the US Cochrane Center (USCC) by the following deadlines if they are to be included in the next issue of CENTRAL:

<u>Deadline</u>	<u>Issue</u>
23 December 2004	Issue 2, 2005
25 March 2005	Issue 3, 2005
24 June 2005	Issue 4, 2005
2 September 2005	Issue 1, 2006

2. What to submit

2.1 All records in specialized register

Each quarter, the RGC/TSC should submit all records in the Group's specialized register that they wish to be included in CENTRAL, even if they have done so previously. It is not necessary for the RGC/TSC to separate records that have been modified or added to the register since the previous submission from those that are staying the same or were included previously. CENTRAL ID numbers, if they have been assigned through downloading from CENTRAL, should not be removed from the records before submission to the US Cochrane Center. If an updated specialized register is not submitted to the US Cochrane Center the previously submitted version of the register is included in CENTRAL.

2.2 Specific data fields

2.2.1 Required fields for CENTRAL

Three fields must be completed for a record to be published in CENTRAL: year of publication, title, and source. In addition, the contents of the publication year field must be greater than 1000 and less than or equal to the current year. There are no rules relating to the contents of the title or source fields. For the remaining fields in specialized registers, Update Software has no requirements with regard to content.

MEDLINE Unique identifiers may be stored in specialized registers in a separate field from other electronic bibliographic database identification numbers or mixed together in the same field with other IDs. If the MEDLINE unique identifiers are stored separately from other IDs, this should be indicated by listing the field number in which (only) the MEDLINE UIs are stored beside 'MEDLINE Unique Identifier' on page 3 of the Submission Form. In this case, the field number corresponding to the field in which other IDs are stored should be listed beside 'Other ID#' on page 3 of the Submission Form. If the MEDLINE UIs are mixed in the same field with other IDs, this should be indicated by listing the field number in which these mixed IDs are stored beside 'Other ID #' on page 3 of the Submission Form. This approach will facilitate future development of a system in CENTRAL whereby MEDLINE accession numbers are published in a separate field from other accession numbers. This separate publication will allow for greater flexibility and ability to search for and identify MEDLINE records. This may, in turn, facilitate duplicate checking in specialized registers when an updated search of MEDLINE is completed.

The National Library of Medicine (NLM) is adopting the PubMed Unique Identifiers (PMID) as the main accession number for all MEDLINE records and may phase out the MEDLINE UI at some point in the future. The CENTRAL Advisory Group is currently reassessing which MEDLINE fields to publish in CENTRAL, and in this review both the UI and the PMID will almost certainly be included for publication on CENTRAL. However, this change will require development work and therefore may not be implemented until the final Cochrane Library publication arrangements have been decided. Therefore, at this time, while the PMIDs can be included as a separate field in specialized registers submitted to the USCC, this field may not be published, at least not for the next few issues of *The Cochrane Library*. If PMIDs are included in a register, the field number corresponding to the field in which PMIDs are stored should be listed beside "PMID" on page 3 of the Submission Form.

When fields are already included in a specialized register, they should be submitted, in the formats described below:

For reports published in journals, the required data fields, where available in a register, are:

- Author(s)
- Title of report
- Journal
- Date of publication
- Abstract
- Volume
- Issue
- Pages

These fields should also be used for reports from conference proceedings that are published in journals or journal supplements.

For reports from conferences that are published in special conference proceedings (i.e., not in journals or journal supplements), the required data fields, where available in a register, are:

- Author (s)
- Title of report
- Full name of conference
- Conference date
- Conference location
- Year in which conference proceedings were published
- Pages, if appropriate

For reports published in book chapters, the required data fields, where available in a register, are:

- Author (s)
- Title of report
- Full name of book
- Year in which book was published
- Pages

For unpublished studies, the required data fields, where available in a register, are:

- Lead or coordinating investigator
- Study title
- Source of further information on the study (e.g., a contact address) *If it is uncertain whether the contact information for the relevant investigator should be included in CENTRAL/CCTR, please do not send it.*
- Years in which the study was conducted

(Note: Records with information missing for year of publication, title, or source fields will not be published, per requirements specified above.)

Other information may also be submitted for each record but this must be clearly described by the RGC/TSC on the Submission Form. For example, some specialized registers contain additional details (e.g., keywords) for each study that might be useful to users of CENTRAL, and these fields may also be submitted. On page 3 of the Submission Form, RGCs/TSCs should identify the field numbers for all fields that they wish to be published on CENTRAL. RGCs/TSCs may also have fields in their register that they do not wish to make public (e.g., housekeeping notes). *The only way to ensure absolutely that such fields are not made public is to exclude them from the file submitted to the USCC.*

The USCC staff will create a standardized file for specialized registers that is submitted to Update Software and loaded onto CENTRAL. Use of consistent fields throughout the register is thus essential. The USCC staff will ensure that the appropriate CRG or Field/Network SR Code is added to each record submitted as part of a specialized register before publication in CENTRAL.

RGCs/TSCs who would like additional guidance for developing their specialized registers should consult Appendices 3 and 4 of the Guide for Submission of Hand Search Results. Appendix

3 provides guidelines for manually entering non-MEDLINE journal article citation information into ProCite or other bibliographic databases, and provides definitions for each field to include and the data format specifications for each. Appendix 4 provides guidelines for hand entering the various types of non-journal article reference types, and for each type lists suggested fields to include and suggested contents for the fields. The most appropriate ProCite Workforms to use for the various reference types are also provided.

2.3 Format of submissions

To ensure that submissions will be included in CENTRAL in a complete and efficient manner, please use the following instructions in preparing specialized registers for submission. If these instructions cannot be followed for any reason, please contact the USCC so that possible alternatives can be discussed.

- Software used
 - ProCite users should submit their specialized register as an electronic bibliographic database. Please send the following pairs of files, either .pdx and .pdt, or .dat and .key files, depending on the version of ProCite used;
 - Reference Manager (version 8 or higher) users should send .rmd and .rmx files. Users of earlier versions of Reference Manager should send an .rm database with all necessary .dat files included;
 - EndNote users should send the .enl file;
 - If a tagged text export file will be submitted, please contact the USCC in advance so that the extra effort required to process the file can be arranged. For files submitted as tagged text export files, please use the tags supplied in Appendix 1 if possible. Also include the workform definition if submitting a tagged text export file, especially if a custom workform is being used. **It is essential that the tagged text file is not manipulated in any way after it has been exported;**
- The specialized register should be submitted as a single file, if possible;
- The submitted file should be zipped or compressed (e.g., using a program such as WinZip or PkZip);
- The submitted file should be named with the appropriate CRG or Field/Network SR Code (SR codes are listed in Appendix 2);
- The submitted file should be in PC format (the USCC is currently unable to process Macintosh files);
- A **Submission Form for Specialized Registers** should be sent *concurrently* with the submission of the electronic file (Appendix 3). E-mailed or faxed Submission Forms are preferable; however

other methods of transfer (i.e., post, FTP) are acceptable. Submission Forms in Appendix 3 can be E-mailed directly;

- The file should be E-mailed to the USCC (cochrane@brown.edu) if smaller than 2 MB. If it is larger than 2 MB, FTP must be used. For FTP users, it is very important to distinguish between the ASCII and Binary options on the lower portion of the FTP screen. Always select the ASCII button for transferring a text file (i.e., a file with the extension txt) and select the Binary button for transferring any other type of file (i.e., any program file such as a ProCite or Reference Manager database file or a zip file). The directory of the FTP site used must be provided on the Submission Form. Please try to avoid using FTP sites from which files are deleted after a relatively short time. For example, files uploaded to the Uploads directory of the UK Cochrane Centre FTP server may be deleted after a short time period; this is therefore not a preferred directory for uploading specialized registers. See Appendix 4 for further instructions on using FTP and for a list of Cochrane FTP sites.

3. **Optional: Tagging citations with study design codes**

RGC/TSCs may also choose to differentiate randomized controlled trials (RCTs) from controlled clinical trials (CCTs), by tagging each record with a study design code.

A trial is considered an RCT or CCT only if the individuals followed in the trial were definitely or possibly assigned prospectively to one of two (or more) alternative forms of healthcare using

- *Random allocation or*
- *Some quasi-random method of allocation (such as alternation, date of birth or case record number)*

Studies are classified as randomized controlled trials (RCTs) or controlled clinical trials (CCTs) according to the reader's degree of certainty that random allocation was used to form the comparison groups in the trial. For written reports, if the author(s) state explicitly (usually by some variant of the term "random" to describe the allocation procedure used) that the groups compared in the trial were established by random allocation, then the trial is classified as an "RCT". If an eligible trial has not been explicitly described by the author as randomized, then there is less certainty that it is, in fact, an RCT. This uncertainty is reflected in a different classification: "CCT". The classification "CCT" is thus applied to possible RCTs. It is also applied to quasi-randomized studies where the method of allocation was potentially "random" but could be predicted in advance of allocation (for example, by using alternation, date of birth or case record number). Studies with historical controls are not eligible for the classification CCT as these do not meet the Cochrane 1992 definition. For written reports, all classifications should be based solely on what the author has written, not on the reader's interpretation. Since the classification terms are based on the author's description of the method of allocation used, they are not meant to reflect the actual quality of the allocation procedure. A trial report which simply states that the study participants were randomized is classified as "RCT", despite the fact that the allocation might have been done using a quasi-random process. Conversely, although double-blind trials are nearly always randomized, many trial reports fail to mention this explicitly and such reports should be classified as "CCT". It is the responsibility of those performing systematic reviews to decide which

trials to include and exclude in any given review.

Any citations that have been downloaded from MEDLINE will have a Publication Type field that has been assigned by MEDLINE indexers. The MEDLINE Publication Type code is distinct from the study design code that an RGC/TSC may choose to assign studies within a register. The study design code that is assigned to the report should not be stored in the same field in which the MEDLINE Publication Type field is stored. For ProCite users, Field 39, if currently unused within a database, is the recommended field in which to place the study design code. If a citation cannot be classified as an RCT or CCT, either leave the study design field blank for this citation or classify the citation as “other”. Adding a study design field to a register is optional.

4. Optional: Adding new records/creating the specialized register

The following section aims to help those adding to or creating new specialized registers. Adding records in the manner suggested will help build CENTRAL more quickly and accurately, because it standardizes the CRG or Field/Network register format.

4.1 It is preferable to add new records to a specialized register by downloading the relevant citations from MEDLINE, when they are included in MEDLINE

While it may not be feasible for RGCs/TSCs to download citations that have been manually entered in the past, citations added to specialized registers in the future should be downloaded if possible. Downloading citation information from MEDLINE may take a few minutes to learn, but once learned, it is much quicker than manually entering citation information. Furthermore downloading citation information from MEDLINE will ensure that citation information included in *The Cochrane Library* is accurate (i.e., free from the mistakes that are inevitable with hand entering) and complete (i.e., includes abstracts and keywords).

4.1.1 How to access MEDLINE

MEDLINE can be accessed through a number of different service providers, including the PubMed version of MEDLINE, which is free over the Internet. The instructions for searching MEDLINE and downloading citations depends upon the platform used. The following websites have detailed instructions:

- Silver Platter: www.SilverPlatter.com
- PubMed: <http://www.ncbi.nlm.nih.gov/PubMed/>
- Ovid: <http://www.ovid.com>

For assistance with searching MEDLINE and/or downloading relevant citations, a local librarian, local Cochrane Center, or the USCC should be consulted.

4.1.2 Fields that need to be included in downloaded record

Ensure that the following fields are included in the downloaded file for each citation:

- MEDLINE Unique Identifier (UI)
- PubMed Unique Identifier (PMID)
- Publication Type (PT)
- Date of Publication (DP)
- Journal Name (TA)
- Citation information: volume number (VI), issue number (IP), and initial and concluding page numbers (PG)
- Name(s) of Author(s) (AU)
- Title of Article (TI)
- Abstract (AB)
- MeSH Index Terms (MH)
- Original Title (non-English title) – relevant for non-English language citations only
- Language – relevant for non-English language citations only

Note: For most programs, the above fields will be part of the default download file. However, the file should be checked and, if necessary, the settings changed to default to ensure inclusion of each of the above. The tags shown above are MEDLARS tags, used by, for example PubMed, the free version of MEDLINE available over the Internet. The tags may be different for other MEDLINE providers.

4.1.3 Format for downloaded file

Ensure that the citations that are downloaded from MEDLINE are in ASCII tagged text format, so that they can be easily imported into a bibliographic database such as ProCite. In the ASCII tagged text format, the citation information is preceded by a tag, followed by a colon (e.g., in the PubMed tagged text format, the information about the author is preceded by AU:). It is also possible to upload MEDLINE records directly into a reference management database, using ProCite version 5.

Before downloading the citations, be certain that the “PC version” option is selected. The USCC is currently unable to process Macintosh files.

4.1.4 Copying downloaded citations to a specialized register

When the ASCII tagged text files downloaded from MEDLINE are copied to a specialized register, it is important to ensure that the citation information in the new records is copied to fields in the specialized register in a manner consistent with how other citation information is already stored in the register.

4.2 Adding new records to a specialized register by hand

If the citations are not downloaded from MEDLINE, or if the relevant records are not included on MEDLINE, then the information about the records may be hand entered onto a bibliographic database such as ProCite. When hand entering data into fields, one must be consistent across all records, always placing similar citation information in the same field for all records. In addition, some Groups download records not included on MEDLINE from other databases, when the relevant permissions have been obtained. Please refer to Appendices 3 and 4 of the Guide for Submission of Hand Search Results for additional guidance on manually entering citations.

5. Copyright

As stated elsewhere in this document, records should only be downloaded from bibliographic databases other than MEDLINE and forwarded to the USCC for inclusion in CENTRAL if you have obtained the appropriate permissions from the copyright owners. Otherwise, the citation should be entered by hand. The abstract and keywords should not be hand-entered, unless the appropriate permissions have been obtained, as these are likely to be subject to additional copyright restrictions. The fact that Update Software or others have permission to download records from certain databases, such as EMBASE, for inclusion in CENTRAL does not imply that Groups, Fields or others within or outside the Collaboration also have these rights.

For assistance, please contact your regional Cochrane Center, or:

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