

Frequently Asked Questions

Questions about Clinical Trials Registration

What is the ICMJE policy about trials that began after July 1, 2005?

ICMJE journals will consider trials beginning on or after July 1, 2005 only if registration occurred before the first patient was enrolled (“prospective registration”).

What is the ICMJE definition of an “ongoing” trial?

The ICMJE considers trials that began enrollment before July 1, 2005 to be “ongoing” if the investigators were still collecting, cleaning, or analyzing data as of July 1, 2005.

Ongoing trials require registration before submission to a journal.

What is the ICMJE definition of a clinical trial?

The ICMJE defines clinical trial as any research project that prospectively assigns human subjects to intervention and concurrent comparison/control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include any intervention used to modify a health outcome. This definition includes drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Research projects do not require registration if their primary goal is to assess major unknown toxicity or determine pharmacokinetics (phase 1 trials). In contrast, we think the public deserves to know about trials that could shape the body of evidence about clinical effectiveness or adverse effects. Therefore, we require registration of all trials whose primary purpose is to affect clinical practice (phase 3 trials). Between these two extremes are some clinical trials whose pre-specified goal is to investigate the biology of disease or to provide preliminary data. However, if trials in this “gray zone” prospectively assign human subjects to an intervention and a concurrent comparison group and collect data on health outcomes (including outcomes such as adverse events), investigators should err on the side of registration if they plan to submit the study to an ICMJE journal.

Which clinical trials registries meet all of the ICMJE criteria for an acceptable registry?

The only registries to date that meet all of the ICMJE’s criteria for an acceptable registry are www.clinicaltrials.gov and the ISRCTN Register (<http://isrctn.com>). However, the ICMJE anticipates that a number of additional registries will make changes that result in them also meeting the ICMJE criteria for acceptable registries. When the ICMJE identifies additional acceptable registries, the committee will post the names of these other registries on www.ICMJE.org. Of note, www.clinicaltrials.gov will accept any trial that meets the ICMJE definition of a clinical trial, regardless of where the trial took place and regardless of whether it was associated with an FDA application.

Where can I get information about how to register a trial?

Please refer to <http://prsinfo.clinicaltrials.gov> for information about how to register a trial in ClinicalTrials.gov.

I'm having trouble registering my trial in ClinicalTrials.gov or believe that my trial is not eligible for registration in that registry... What now?

Send an email to register@clinicaltrials.gov with your question or explaining the problems you are encountering.

Are clinical trials registries in languages other than English acceptable to meet the ICMJE's trials registration policy?

The ICMJE discussed the issue of registries in languages other than English at the committee's recent meeting. If the registry included entries for all the appropriate data fields in both English and the other language and met the other criteria (freely accessible, electronically searchable, not-for-profit management), the ICMJE would find it an acceptable registry. The ICMJE is cooperating with the WHO effort and our goal will be to eventually adopt WHO policy with respect to registry language. However, until the WHO has a mechanism in place to solve the problems of searching across registries in different languages, the ICMJE feels that the minimal data items need to be registered in English as well as in the native language of the registry.

Do I need to register a trial if the subjects were health care providers and not patients?

Some trials assign health care providers, rather than patients, to intervention and comparison/control groups. If the purpose of the trial is to examine the effect of the provider intervention on the health outcomes of the providers' patients, then investigators should register the trial. If the purpose is to examine the effect only on the providers (for example, provider knowledge or attitudes), then registration is not necessary.

Questions about ICMJE Membership

How can I join the ICMJE?

The ICMJE (previously known as the Vancouver Group) is not an open membership organization. It is a small working group of general medical journals. Occasionally, the ICMJE will invite a new member or guest when the committee feels that the new journal or organization will provide a needed perspective that is not already available within the existing committee. Open membership organizations for editors and others in biomedical publication include the World Association of Medical Editors www.WAME.org and the Council of Science Editors www.councilofscienceeditors. However, if your journal follows the ICMJE's Uniform Requirements for Manuscripts Submitted to Biomedical Journals and you would like the ICMJE to include it on the list of journals that follow ICMJE policy on www.ICMJE.org, just send an e-mail stating that request. If you include the URL for your journal's web site, we can post a link from www.ICMJE.org to your journal.

Which journals are members of the ICMJE?

Annals of Internal Medicine, Canadian Medical Association Journal, Croatian Medical Journal, JAMA, Nederlands Tijdschrift voor Geneeskunde, New England Journal of Medicine, New Zealand Medical Journal, The Lancet, The Medical Journal of Australia, Tidsskrift for Den Norske Llegeforening, and Ugeskrift for Laeger are the member journals. However, a large number of non-member journals reports that they follow the ICMJE's Uniform Requirements for manuscripts Submitted to Biomedical Journals.

Questions about the Uniform Requirements For Manuscripts Submitted to Biomedical Journals

How do I obtain a print copy of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs)?

The ICMJE does not publish print copies of the current Uniform Requirements. The official and most current document is freely available to the public at on the ICMJE web site. Interested users can print a PDF version of this document from www.ICMJE.org.

Can I translate/reprint the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs)?

The ICMJE welcomes organizations to reprint/translate the URMs into languages other than English for non-profit purposes. However, the ICMJE does not have the resources to translate, to back translate, or to review or approve reprinted/translated versions of the document. Thus, any reprints/translations should prominently include the following statement:

"This is a (insert language name) language translation/reprint of the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals. (insert name of organization) prepared this reprint/translation with support from (insert name of funding source, if any). The ICMJE has not endorsed nor approved the contents of this reprint/translation. The official version of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals is located at www.ICMJE.org. Users should cite this official version when citing the document."

The ICMJE asks that anyone who reprints/translates the Uniform Requirements notify the ICMJE of that reprint/translation by sending an e-mail to the ICMJE secretariat office: claine@acponline.org

How do I cite the Uniform requirements for Manuscripts Submitted to Biomedical Journals?

International Committee of Medical Journal Editors [homepage on the Internet]. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication [insert month/day/year you accessed site] Available from: <http://www.ICMJE.org> .

Which journals follow the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs)?

There are only 11 journals that are official members of the ICMJE: *Annals of Internal Medicine*, *Canadian Medical Association Journal*, *Croatian Medical Journal*, *JAMA*, *Nederlands Tijdschrift voor Geneeskunde*, *New England Journal of Medicine*, *New Zealand Medical Journal*, *The Lancet*, *The Medical Journal of Australia*, *Tidsskrift for Den Norske Llegeforening*, and *Ugeskrift for Laeger*. However, a large number of journals follow the URMs. A list of journals that have contacted the ICMJE to request listing as a publication that follows the URMS is available at www.ICMJE.org. There may be journals that follow the URMs that do not appear on this list. Users should also be aware that individual publications and their editors may have individual interpretations of and implementation of URM recommendations. The ICMJE cannot verify how closely listed journals follow the many specific recommendations contained within the URMs. If authors have questions about a particular journal to which they are considering

submitting their work, they should consult the “Information for Authors” or the editorial office of that journal.

Questions about Other Issues

What is the contact information or how do I submit an article to a specific journal?

Individuals with specific questions about a specific journal must contact that journal directly. The ICMJE does not maintain a directory of journals. However, some journals have included their internet addresses when requesting posting on the ICMJE’s list of journals that follow the Uniform Requirements for manuscripts Submitted to Biomedical Journals. However, if the internet address is not on the list, the ICMJE will not be able to provide you with this information. We suggest that you search for the journal of interest on the internet or consult the library at your institution.

How do I format a specific citation?

The ICMJE no longer publishes a list of reference formats, but instead recommends that authors follow the ANSI standard style adapted by the National Library of Medicine (NLM) for its databases. For samples of reference citation formats, authors should consult http://www.nlm.nih.gov/bsd/uniform_requirements.html .