

**Question and Answer Sheet\*:**  
**ICMJE Requirement for Clinical Trial Registration**  
**(International Committee of Medical Journal Editors)**

1. What is the ICMJE?

The International Committee of Medical Journal Editors (ICMJE) is a group of medical journal editors that has been setting publication guidelines for the submission of manuscripts to medical journals since 1978. Examples include such journals as, the Lancet, Journal of the National Cancer Institute, and The New England Journal of Medicine.

Source: <http://www.icmje.org/>

2. What is the requirement?

Effective July 1, 2005, ICMJE will consider a trial for publication only if it has been registered before the enrollment of the first patient.

3. Who registers the clinical trial on a free publicly accessible website?

“Multi-site trials and multi-sponsor trials are susceptible to duplicate registration, thus care must be taken in how the trials are registered. For multi-sponsor trials it is the [lead sponsor](#) who should take responsibility for registration. It is critical that investigators and sponsors work together to ensure that a trial is registered once and only once. “

Source: <http://prsinfo.clinicaltrials.gov/>

4. What about ongoing studies?

ICMJE will consider for publication ongoing trials that are registered before September 13, 2005.

5. How does ICMJE define clinical trial?

“Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical intervention means any intervention used to modify a health outcome. The definition includes drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

6. What Clinical Trials that meet the ICMJE definition above need to be registered?

- § All “clinically directive” trials must be registered, all trials whose primary purpose is to affect clinical practice
- § Phase III or IV
- § Trials that have at least one prospectively assigned concurrent control or comparison group

Examples: trials that test a clinical hypothesis about health outcomes (Is drug X as effective as drug Y in the treatment of heart failure?).

7. What Clinical Trials do not require registration?

- § Trials whose primary requirement is to assess major unknown toxicity
- § Trials whose primary requirement is to assess pharmacokinetics (Phase I)

\*Information was obtained from:

Website: [http://www.icmje.org/clin\\_trialup.htm](http://www.icmje.org/clin_trialup.htm)

Article: “Is This Clinical Trial Fully Registered?”

8. How does ICMJE decide if they will publish?

Each journal editor will decide on a case-by-case basis about reviewing unregistered trials in this category. Authors whose trial is unregistered will have to convince the editor that they had a sound rationale when they decided not to register their trial.

9. What information must be included on a website to register the trial?

1. The registry must be electronically searchable and accessible to the public at no charge.
2. "ICMJE supports the WHO minimal data set and has adopted it as the ICMJE's requirement." It includes 20 fields ([www.icmje.org/clin\\_trialup.htm](http://www.icmje.org/clin_trialup.htm)).

10. How long is this policy in effect?

The ICMJE will maintain this policy for the next two years. They will then review the experience.

**11. As an investigator what does this mean to me?**

**If you wrote the protocol and intend to publish, your phase III & IV or any clinical trial whose primary purpose is to affect clinical practice, must be posted on a public website meeting the ICMJE or WHO criteria in order to publish in a medical journal.**

12. How do I post a clinical trial of [www.clinicaltrials.gov](http://www.clinicaltrials.gov)?

1. Complete the CT website posting form (located at [http://www2.kumc.edu/researchinstitute/cra/craforms/icmje\\_g\\_a.doc](http://www2.kumc.edu/researchinstitute/cra/craforms/icmje_g_a.doc))
2. E-mail the form and attachments to [ksmilor@kumc.edu](mailto:ksmilor@kumc.edu)

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Article: "Is This Clinical Trial Fully Registered?"