

# International Committee of Medical Journal Editors (ICMJE) REQUIREMENTS FOR REGISTRATION OF CLINICAL TRIALS

**Does the PI assign human participants to one or more arms or interventions to evaluate the effects on health-related outcomes?** Interventions include: drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process of care changes. Health outcomes include: biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

No: the study may, but is not required, even by ICJME to register.

Really can't tell? Review with PI or Diane Wilson 764-0634 ([dlehman@umich.edu](mailto:dlehman@umich.edu)); when in doubt, register. "Those who are uncertain whether their trial meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal."

Yes, ICJME requires registration of this study.

**SPECIAL CASE #1: Do I need to register a trial if the subjects were health care providers?** 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.

## OK, when must it be registered?

### Was the trial ongoing on July 1, 2005?

**NO:** ICMJE journals will consider trials beginning on or after July 1, 2005 **only if registration occurred before the first patient was enrolled ("prospective registration").**

**YES:** 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.**

Special Case for Timing: What if I register my device trial in ClinicalTrials.gov and it is covered by the delayed posting ("lock box") provision of Food and Drug Administration Amendments Act of 2007 (FDAAA), meaning that the registered information is not publicly accessible immediately following registration? The ICMJE does require public, prospective registration of clinical trials of all interventions, including devices. So, either don't use delayed posting OR register in another trial registration site.

## ClinicalTrials.gov and What it Means to You (October 2015)

Principal investigators or sponsors **must** register all “applicable clinical trials” as defined by the Food and Drug Amendments Act (generally Phase II – IV studies of FDA regulated drugs, devices or biological). Each trial only gets registered once, so each trial must have a “Responsible Party” who will register the trial. Industry initiated studies generally are registered by the industry sponsor, but if the PI is the initiator or holds the IND or IDE, then s/he must register the trial. Registration takes 1- 2 hours, with brief annual upkeep.

There are other important reasons someone might want to register in ClinicalTrials.gov.

- International Committee of Medical Journal Editors requires that all clinical trials (broadly defined to include all sorts of prospective studies, even process of care, dietary or behavioral studies, if they are measuring health-related outcomes) register prior to enrolling first participants.
- NIH’s definition of clinical trial includes behavioral input and behavioral outcomes as well if they are “health-related. NIH currently “encourages” all NIH-funded trials to register and report results
- CMS has a new billing rule as of 1/1/2014 which requires ClinicalTrials.gov registration numbers NCT#s in any bills for services associated with Clinical Trials.

IF the study is required by law to register, then the informed consent for the study must use the regulatorily prescribed language, which is found in the eResearch template. Only “applicable clinical trials” as defined by the law should use the regulatory language in the informed consent provided in the template about ClinicalTrials.gov. Studies which are being registered “voluntarily” rather than “as required by law”, may omit any reference to ClinicalTrials.gov or create another sentence, but need not use those sentences.

Among Applicable Clinical Trials, a smaller subset, those that involve FDA approved drugs, devices or biological must post **results**, patient flow, and adverse events in ClinicalTrials.gov as well. If a proposed NIH policy goes into effect, all NIH funded clinical trials will be required to post results as well. Results reporting averages 40 hours of work.

The UMMS Office of Regulatory Affairs can help. Contact Diane Lehman Wilson at 734 764-0634 or [dlehman@med.umich.edu](mailto:dlehman@med.umich.edu). While the law covering what does and doesn’t need to be registered has been in effect since 2007, enforcement pressure is growing, and the informed consent language is one tool that FDA may choose to use in that effort. Much more information is available at [prsinfo.clinicaltrials.gov](http://prsinfo.clinicaltrials.gov).