

ClinicalTrials.gov is the national registry of federally and privately supported research studies conducted in the United States and around the world.

The basic rationale for ClinicalTrials.gov is that it can be a tool to improve transparency and reduce duplication of effort --- Deb Zarin, the Director of ClinicalTrials.gov even recommends that as part of the risk-benefit analysis the IRB performs, it should check ClinicalTrials.gov as well as doing a literature search before approving studies to see that they do not duplicate other effort.

Three reasons exist to register a study in ClinicalTrials.gov: to find new participants, to retain the ability to publish later and because the law requires it. The first reason is purely discretionary and can apply to any study.

The second is established by the policy of the International Committee of Medical Journal Editors (ICMJE), which says one must register clinical trials before enrolling the first participant. Please note that the ICMJE definition of clinical trial is very broad and includes treatments involving process of care, behavioral, and nutritional changes if they will measure a health outcome. Within the last year New England Journal of Medicine alone has turned away dozens of articles on this basis. But even while this incentive is getting stronger, this reason still is “optional”, in that it’s not a legal requirement.

The third reason to register a study is that for “Applicable Clinical Trials”, basically non-Phase I or feasibility studies that involve an FDA regulated item, the Responsible Party is required to register them by **law!** Some will merely need to *register* – because they are FDA regulated but not yet approved; others are required by law to register **and** post results – because they involve an already FDA approved drug, device or biologic. Either way, these studies, required by law to register, must use the new informed consent language, verbatim, which the template includes in Section 10.

Recent FDA guidance says one should NOT use the special informed consent language if the trial is NOT required by law to register. Therefore IRB staff and members should consider this question in approving a study.

Regulatory Affairs has reviewed the 162 studies approved since this regulation went into effect. Of 44 without the language, only 7 needed it, which is a pretty good rate! Thank you! But of the 118 that did have the language, it looks like a greater number didn’t need it. (We’re still checking these.)

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