U-MIC TRANSCRIPT
ClinicalTrials.gov: fundamentals

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

ClinicalTrials.gov is a tool to improve transparency and reduce duplication of research. ClinicalTrials.gov is even recommended to be used as part of the IRB's risk-benefit analysis, as it provides information in real time about competing trials and may contain more recent or complete results or adverse event data than a literature search would yield.

Four main reasons exist to register a study in ClinicalTrials.gov: to find new participants, to retain the ability to publish findings, and because the law or Federal policy requires it. The first reason is purely discretionary and can apply to any study, whether it is observational or a trial.

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. Since our faculty generally want to publish the findings from their research, this is an important driver but is not a legal requirement.

The third reason to register a trial is that for "Applicable Clinical Trials or (ACTs)", basically non-Phase I or early device feasibility studies that involve an FDA regulated item, the Responsible Party is required by federal law and regulation (42 CFR 11) to register them *and* report results within one year of data collection completion**!** These trials must use the new informed consent language, verbatim, which the IRBMED informed consent document template includes in Section 10.
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 trial.

Finally, since 2017 NIH policy has required all NIH funded trials (very broadly defined) which began after 1/17/2017 and whose grant applications were submitted after that date to register *and* report results. They too must refer to ClinicalTrials.gov registration in their informed consent language. Other funders, both public and private, may have similar requirements. For those that are not drug and device trials, an alternative ClinicalTrials.gov reference is included in the help portion of the template Informed Consent Document.

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