

KESSLER FOUNDATION

Policies and Procedures Manual IRB

SUBJECT: Registering Clinical Trials at ClinicalTrials.gov	POLICY # 5036
APPROVED:	EFFECTIVE DATE:
Jeanne M. Zanca, MPT, PhD IRB Chair	March 29, 2006
John DeLuca, PhD Senior Vice President for Research	REVISIED DATE:
	<u>November 15, 2023</u>

PURPOSE

The registration of clinical trials in a free, publicly accessible forum can provide patients, physicians, researchers and funding agencies with information on what trials are currently being carried out. Through a trial registry patients (and their physicians) can learn of trials for which they may be eligible. Trial registration can avoid duplication of research efforts and can help counteract the bias that occurs when studies with negative results go unpublished.

The NIH has developed a web-based trial registry ClinicalTrials.gov. Starting in 2007, the FDA required all pre-marketing Phase 2 and 3 trials of drugs and devices to be registered on this site. Moreover, many scientific journals will not publish the results of clinical trials that have not been registered on a publicly accessible trial registry before the first subject is enrolled. This is the formal policy of the International Committee of Medical Journal Editors (ICMJE)¹ and has been adopted by many U.S. and international journals in the biomedical and behavioral sciences.

The purpose of this Kessler Foundation IRB policy is to comply with the FDA and the ICMJE policies by requiring all applicable clinical trials be registered on ClinicalTrials.gov.

POLICY

Definition of Trials Requiring Registration

The Kessler Foundation's IRB requires that all research studies that meet the current ICMJE definition of a clinical trial be registered on ClinicalTrials.gov before the first subject is enrolled:

"The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary

interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.”¹

According to ICMJE recommendations “secondary data analyses of primary (parent) clinical trials should not be registered as separate clinical trials, but instead should reference the trial registration number of the primary trial.”¹

Research designs where the exposure or intervention is not controlled by the researchers, such as observational studies of outcomes associated with health care delivery, are not required to be registered according to ICMJE. However, researchers conducting observational studies may still choose to register their studies to prevent issues associated with selective publication, avoid unnecessary duplication of research effort, and inform the public of ongoing research opportunities.

Timing of Registration

Note that ICMJE uses the date trial registration materials were first submitted to a registry as the date of registration.¹ Registration must take place before the first participant provides informed consent to enroll in the study.

Contact Person for Registration

Researchers planning to register a study with ClinicalTrials.gov should contact Kessler Foundation’s designated ClinicalTrials.gov administrator, Matthew Weiner (mweiner@kesslerfoundation.org).

Maintenance of ClinicalTrials.gov Records

As a general rule, information submitted to ClinicalTrials.gov is expected to be updated at least once every 12 months. Certain situations may require a more rapid update. Examples include (but are not limited to):

- Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status.
- Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date.
- If a protocol is amended in such a manner that changes are communicated to human subjects in the clinical trial, the regulations require that updates to any relevant clinical trial information be submitted not later than 30 calendar days after the protocol amendment is approved by the IRB of record.

See regulations published at 42 CFR 11.64(a)(1)(ii)³ for definitive guidance on the required timing of updates to project information.

Past Policy Note

At the time of the original Kessler Foundation IRB policy (effective 2006) on clinical trial registration, studies that did not have “at least one prospectively assigned concurrent control or comparison group” were not required by ICMJE to be registered. However, ICMJE later expanded the definition of clinical trials requiring registration to include those that do not necessarily involve a concurrent

comparison or control group.² The Kessler Foundation Institutional Review Board policy was updated in 2023 to match the expanded ICMJE definition.

Investigators wishing to be updated by ICMJE on changes in their recommendations may provide contact information at <https://www.icmje.org/recommendations/subscribe-to-changes/>.

REFERENCES

1. International Committee of Medical Journal Editors. "Clinical Trials." Accessible at: <https://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>. Accessed November 15, 2023.
2. International Committee of Medical Journal Editors. "Clinical Trials." Accessible at: <https://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>. Accessed November 15, 2023.
3. "When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected?" Accessible at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-11/subpart-D/section-11.64>. Accessed November 15, 2023.