Why Register My Study?

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According to the World Health Organization (WHO), “The registration of all interventional trials is a scientific, ethical and moral responsibility.”

According to the World Medical Association (WMA) Declaration of Helsinki (2013): it is stated that “Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.” and that “Researchers have a duty to make publicly available the results of their research .... Negative and inconclusive as well as positive results must be published or otherwise made publicly available”.

Registration may be required by law and/or policy if any one (or more) of the following is true:

Required by Law

Your study involves a drug or device:

FDAAA (U.S. Public Law 110-85, Food and Drug Amendments Act of 2007) requires registration of all Applicable Clinical Trials in ClinicalTrials.gov

- Applicable clinical trials generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE).

- FDAAA establishes penalties for failure to comply with registration or results submission requirements. Penalties include civil monetary penalties and, for federally funded studies, the withholding of grant funds.

Required by Your Funding Source

The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (effective January 2017) establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered and results information is submitted to ClinicalTrials.gov.

All competing applications (new and renewal) and progress reports for NIH grants (including cooperative agreements) supporting applicable clinical trials must include a certification of compliance with FDAAA. This includes applications where the trial has not yet begun (e.g. is proposed) or is not yet required to be registered (e.g. less than 21 days since first subject was enrolled), as well as applications and progress reports that include an on-going trial that is already registered in ClinicalTrials.gov.

Required for Journal Publication

- Required for Journal Publication: You intend to publish an article about your study methods and/or outcomes. The International Committee of Medical Journal Editors (ICMJE) requires, and recommends that all medical journal editors require, as a condition of consideration for publication, registration of [all] clinical trials in a public trials registry at or before the time of first patient enrollment.

- 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 cause-and-effect 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, behavioural 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.”

Required for Billing

For a Qualifying Clinical Trial (QCT): You intend to bill insurance for routine costs of care for study participants.

The Center for Medicare and Medicaid Services (CMS) requires a clinical trial identifier (NCT#) be reported on all billing claims for items/ services related to a qualifying clinical trial. If your study will bill routine costs to Medicare or any other insurer, the study must be registered on ClinicalTrials.gov to obtain the NCT#.

Qualifying Criteria (All three criteria must be "Yes"):

1. Evaluates a medicare benefit
2. Has therapeutic intent
3. Enrolls diagnosed beneficiaries

Deemed Automatically Qualifying Trial (Any one criteria must be "Yes"):

- Is funded/supported by NIH, CDC, AHRQ, CMS, DOD or VA
- Is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
- Has an IND number: Trial conducted under an investigational new drug application (IND) reviewed by the FDA
- Trial is exempt from having an IND

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

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