

Section 31: Protocol Registration Requirements

U.S. Public Law 110-85, along with the International Committee of Medical Journal Editors (ICMJE), requires registration of clinical trials on a publicly-accessible database. The National Library of Medicine maintains the preferred registry (ClinicalTrials.gov) at www.clinicaltrials.gov.

As an NCI-designated comprehensive cancer center, DF/HCC is also required to register all interventional, observational and correlative trials, regardless of funding type, to the Clinical Trials Reporting Program (CTRP).

31.1 Clinicaltrials.gov

Protocol Registration

Clinicaltrials.gov requires that registered trials be managed and validated locally before they are published within the system. Registration should occur *after* IRB approval and *before* the first participant is enrolled.

There is shared responsibility between the sponsor and lead investigator to register the trial. Investigators and study staff may refer to the chart below for guidance.

RESEARCH TYPE	PROCEDURES
Industry-initiated and-funded	Contact the pharmaceutical sponsor to determine the registration responsibility.
Federally funded (includes NIH, CTEP, and NCI Cooperative Groups)	Contact clinicaltrials.gov directly. Instructions on how to submit information are available at http://prsinfo.clinicaltrials.gov
In-house, investigator-initiated	Contact the CTEO or the clinicaltrials.gov registration coordinator at your home institution to facilitate the registration process and resolve questions associated with trial information.

Protocol Registration Maintenance

Public Law 110-85 and ICMJE also require the routine update and verification of the information posted. Protocol records need to be updated within 30 days of any recruitment changes and the information must be verified every 6 months.

Please refer to the CTEO Tip Sheet: *Updating Information on Clinicaltrials.gov* for additional information.

Posting Protocol Results

Public Law 110-85 also requires the posting of results on clinicaltrials.gov. Results are required to be posted within one year from the completion of the primary outcome. For additional information, please refer to [DF/HCC SOP SS-301](#).

31.2 Clinical Trials Reporting Program (CTRP)

NCI's Clinical Trials Reporting Program (CTRP) requires the registration of trials within 21 days after activation. This process is centrally maintained within the Quality Assurance Office for Clinical Trials (QACT) and the Clinical Trials Education Office (CTEO).

Contact the CTEO at cteo@dfci.harvard.edu with any questions regarding the CTRP process.