

CLARIFICATION Regarding NCI's Clinical Trials Reporting Program

NCI's Clinical Trials Reporting Program (CTRP) is an additional requirement and does not replace the requirements for registration with clinicaltrials.gov.

ClinicalTrials.Gov

ClinicalTrials.gov was developed to facilitate the registration of trials in accordance with both the International Committee of Medical Journal Editors (ICMJE) and the Food and Drug Administration Amendments Act of 2007 (FDAAA) **requiring** prior entry of clinical trials in a **public** registry. The registration and maintenance of the information falls on the shoulders of the trial sponsor. Clinicaltrials.gov was designed to be used by the **general public** as a means to search for clinical trials with the goal of transparency of information and not based on the outcomes of the trials themselves.

ICMJE and FDAAA however, have different registration requirements. These differences are outlined below:

ICMJE: Requires Phase I and beyond trials to be registered PRIOR to participant enrollment and verified every 6 months

FDAAA: Requires Phase II and beyond trials to be registered within 30 days of patient enrollment and verified every 12 months

The DF/HCC standard practice is to register all PI-Initiated trials regardless of the Phase to ensure that both requirements are met. Currently the Clinical Trials Education Office (CTEO) helps facilitate this process by notifying study teams of the registration requirements and entering in the initial registration information. However, maintenance of the information posted on clinicaltrials.gov does lie with the Overall PI (or designee) in the case of PI-Initiated trials.

Clinical Trials Reporting Program (CTRP)

NCI established the Clinical Trials Reporting Program in response to a recommendation of the Clinical Trials Working Group (CTWG). The CTWG was convened to advise the National Cancer Advisory Board (NCAB) on "whether, and in what ways, the NCI-supported national clinical trials enterprise should be restructured to realize the promise of molecular medicine for advancing oncologic clinical practice in the 21st century". The report (http://integratedtrials.nci.nih.gov/ict/CTWG_report_June2005.pdf) contains recommendations intended to support a transparent clinical trials enterprise that integrates the individually strong components of the current system into a cross-disciplinary, scientifically-driven, cooperative research effort. The NCAB approved the CTWG Report in June 2005.

The purpose of the Clinical Trials Reporting Program is to provide data that **assists NCI** in more efficiently coordinating research efforts to optimize our nation's investment in cancer research.

We recognize that NCI grantees currently provide data for various NCI programs. CTRP is working with these NCI programs to integrate these data and eliminate redundant NCI data requests.

As stated in the Listserv below, the **Quality Assurance Office for Clinical Trials** will be coordinating and registering all trials reviewed by the DFCI IRB which meet the reporting criteria.

In an effort to facilitate the CTRP registration process and clarify the DF/HCC policy on the release of research protocols, DF/HCC SOP PM-412: Confidentiality of Research Protocols has been revised. Please see attached.

For more information regarding DF/HCC's process for trial registration, please contact Alyssa K. Dellacroce, QACT Assistant Director, adellacroce@partners.org or (617) 632-3731.

Please see <http://ctrp.nci.nih.gov/> for more NCI information on CTRP.

To access the revised SOP directly from the DF/HCC intranet: <http://www.dfhcc.harvard.edu/clinical-research-support/>

DF/HCC's Process for NCI's Clinical Trials Reporting Program

As of January 5, 2009, participation in NCI Clinical Trials Reporting Program (CTRP) is required. To facilitate this process within DF/HCC, the **Quality Assurance Office for Clinical Trials** will be coordinating and registering all trials reviewed by the DFCI IRB which meet the reporting criteria.

For the first quarter of 2009, CTRP is limiting clinical trial registrations to:

- Five participating sites only
 - Dana-Farber/Harvard Cancer Center
 - Mayo Clinic Cancer Center
 - Robert H. Lurie Cancer Center at Northwestern University
 - St. Jude's Children's Research Hospital
 - Wake Forest Comprehensive Cancer Center
- Interventional trials only (all Phases, both drug and device), not observational or ancillary/correlative
- New trials (i.e., trials that received IRB approval to begin enrolling patients January 1, 2009 and later)
- Those trials that are NOT registered with NCI through other means (e.g., CTEP, DCP, CCR). For instance, Cooperative Group trials do not need to be registered.

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