DF/HCC
DANA-FARBER / HARVARD CANCER CENTER

Clinical research

DF/HCC has one of the largest clinical research initiatives in the country, taking a unified approach to approving, activating, monitoring, and supporting the cancer-related clinical trials conducted at our member institutions. As an NCI-designated Comprehensive Cancer Center, clinical trials efforts must comply with federal guidelines for cancer-related clinical trials.

The following types of studies must be reviewed by DF/HCC prior to activation:

Ancillary, Correlative, Diagnostic, Early Detection, Epidemiologic, Observational, Outcomes, Prevention, Screening, Supportive Care, Therapeutic

Clinical Trials Process

The interactive clinical trials protocol lifecycle visualization

The scientific review of clinical trials at DF/HCC is designed to ensure that activated trials are of high scientific merit, a priority to the relevant disease program, and will accrue the targeted number of research subjects.

Prior to formally submitting a trial for review and approval, there is an extensive and interactive vetting process. This includes review of the trial concept and draft protocol at the institutional level as well as by the relevant DF/HCC research program. While the review process may vary depending on the research program, no protocol is forwarded for scientific review unless the protocol packet includes a signed letter of support by the program leader that confirms the trial is of scientific importance, does not overlap with existing trials, and can be completed within the desired time frame.

Submitted trials are reviewed by the Scientific Review Committee (SRC), as well as several specialty subgroups such as radiation safety, research pharmacy, nursing, and biostatistics. Once approved by the SRC, the Institutional Review Board (or IRB)—a single review board for all cancer-relevant research as required by the NCI for all Comprehensive Cancer Centers, and consisting of multiple panels to support the large number and diversity of trials taking place at DF/HCC—conducts its initial review. When approved by the IRB, the trial is activated. Activated trials are reviewed annually on the basis of scientific merit and accrual rate.

Learn More

www.dfhcc.harvard.edu/clinical-research-support

The DF/HCC website has a wealth of information and resources about clinical research. Forms, information, updates, and toolkits are available. For more information visit our website to find, access and learn more about the following:

- Document Library - Search all Clinical Research documents in one convenient place
- Trial lifecycle - Forms, policy, guidance, and links intuitively organized by steps in the path toward an accepted trial
- OncPro - New user registration and useful information
- Educational Materials - Guidance for new DF/HCC researchers and principal investigators
- Full Contact List - Find the right person to talk to with this complete list of all CRS staff

Clinical Research Support Offices

CLINICAL RESEARCH AGREEMENTS OFFICE

The Clinical Research Agreements Office works with industry to negotiate budgets and contracts for PI-initiated trials. For CHB and BIDMC-led trials, the Office works closely with clinical trials negotiators at their respective institutions.

CLINICAL TRIALS BUSINESS OFFICE (CTBO)

The CTBO provides a centralized, comprehensive program of support for sponsored clinical research. Offices at lead sites work with principal investigators and their teams to evaluate budgetary and financial implications for new studies. The CTBO also prepares and negotiates financial terms with industry sponsors; and manages post-award finances including invoices, accounts receivable, funds, distributions, and financial reports.

OFFICE FOR HUMAN RESEARCH STUDIES (OHRS)

OHRS coordinates all SRC and IRB committees, and provides regulatory guidance and resources to clinical investigators and their support staff.

The Office also maintains the Oncology Protocol System with current copies of protocol and consent documents.

CLINICAL TRIALS RESEARCH INFORMATICS OFFICE

The Clinical Trials Research Informatics Office specifically addresses the growing technological needs of the clinical trials research community. The office provides a collaborative, responsive, integrated and focused approach to all aspects of systems development and support. Areas of particular interest include the continued expansion of OnCore, enhanced integration with Epic and other DF/HCC member institution systems, and clinical trials reporting for the Cancer Center Support Grant (CCSG).

OFFICE OF DATA QUALITY

The Office of Data Quality focuses on quality assurance, quality control, and quality improvement processes. The office is also responsible for clinical trials auditing, data safety monitoring, and overall data quality, as required by the Cancer Center Support Grant.

LOOKING FOR A FORMER POLICY?

The document library includes all clinical research support documents, including DF/HCC SOPs, forms, guidances, and other materials, and is searchable by type of document. To view archived versions of all documents, use the Archive Only option, and use the filter menu to search for specific documents.

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ABOUT DF/HCC

Dana-Farber/Harvard Cancer Center is the largest National Cancer Institute-designated Comprehensive Cancer Center in the nation. Founded in 1998, DF/HCC is an inter-institutional research enterprise that unites all of the cancer research efforts of the Harvard-affiliated community. The primary goal of the Cancer Center is to encourage and promote collaborative interactions and translational research that will lead to new approaches to cancer prevention, diagnosis, and treatment.