

Section 29: Clinical Trials Education Office (CTEO)

Education in the conduct of human research and clinical trials is essential to protecting the rights and welfare of individuals participating in cancer research studies. In recognition of this principle, the CTEO provides centralized education services for the DF/HCC research community. The CTEO offers initial and continuing education opportunities designed to support, develop and maintain a standardized body of knowledge and best practice methodology.

In addition to the compulsory training in human participant protections, the CTEO curriculum includes interactive workshops, traditional lectures and seminars, and online instruction to enhance the overall knowledge of DF/HCC investigators and study staff. The multi-faceted programs aim at ensuring Good Clinical Practice (GCP) in the conduct of cancer-related research and compliance with all applicable Federal regulations, state laws and local guidelines.

29.2 Programs for Clinical Investigators

New Clinical Investigator Training

This one-to-one training session, designed for investigators conducting clinical research for the first time or those new to DF/HCC, provides an introduction to NCI requirements, DF/HCC policies, and DFCI IRB guidelines and reporting requirements pertinent to the research initiatives at DF/HCC. New clinical investigators are required to complete this one-time training prior to participating in DF/HCC research. For more information or to schedule a training session, contact the CTEO at cteo@dfci.harvard.edu or 617-582-8480.

DF/HCC Clinical Investigator Education Series

The DF/HCC Clinical Investigator Education Series – a quarterly forum - utilizes lectures, interactive discussions and/or case studies to disseminate:

- Underlying principles and procedures for conducting clinical trials
- Current information on topics related to the conduct and management of oncology clinical trials
- Best practice information, including meeting the standards of Good Clinical Practice (GCP), that can be incorporated into the workplace

This category 1 CME approved series runs from September through June. For more information on the series, including upcoming topics and category 1 CME information, contact the CTEO at cteo@dfci.harvard.edu or 617-582-8480.

29.1 Programs for Study Team Members

As a service to the DF/HCC disease and discipline-based programs, the CTEO takes a proactive approach and works with other research entities to provide initial and ongoing education to study team members. To ensure the safe conduct of clinical trials within DF/HCC, the following educational opportunities are available to DF/HCC study team members.

Orientation Workshops for New Research Staff

A core level of training is available for study team members with ≤ 6 months of clinical research experience or for those new to DF/HCC. Sessions for new study team members, emphasizing the essentials of trial management, provide an overview of how clinical trials are conducted at DF/HCC and give study staff an opportunity to ask questions about their responsibilities.

The series is offered monthly, on a rotating schedule, at the Dana-Farber Cancer Institute, for institutions in the Longwood Medical Area, and at the Massachusetts General Hospital (MGH).

Registration is required as seating may be limited. The workshop schedule is posted to the [CTEO website](#) on a quarterly basis.

Workshops last approximately 1-1.5 hours. Attendees receive a certificate of attendance for each workshop completed.

Research Education Series

This continuing education series is designed for study team staff with ≥ 6 months of clinical research experience. Topics focus on ethical issues in clinical research, barriers to day-to-day trial management and clarifications about how to apply regulations and guidelines to current practice. These sessions are generally offered at the Dana-Farber Cancer Institute, for institutions in the Longwood Medical Area, and at the MGH Cancer Center Protocol Office.

Registration for the research series is strongly encouraged as seating may be limited. The series schedule is posted to the [CTEO website](#) on a quarterly basis.

In an effort to improve educational offerings for experienced staff involved in clinical trials, contact hours are offered when applicable.

29.3 Professional Certification of Study Team Members

Professional certification of study team members is encouraged for individuals with \geq two years of clinical research experience. DF/HCC staff may sit for either the Clinical Research Coordinator examination (Association of Clinical Research Professionals) or the Clinical Research Professional examination (Society of Clinical Research Associates). Questions and/or requests for study materials should be forwarded to the CTEO at cteo@dfci.harvard.edu or 617-582-8480.

29.4 eLearning Center

The objective of CTEO **eLearning Center** is to ensure that DF/HCC investigators and study team members have access to clinical trials education at a time, and in a manner, convenient to them.

eModules

Focusing on a variety of topics related to human participant research at DF/HCC, these brief voice-over Powerpoint presentations are a quick and easy way to review basic information and expectations about DF/HCC research processes and compliance.

More eModules are in development. If you have a suggestion for a new topic, or have any comments, contact the CTEO Director.

Presentation Archive

Learners can tab through select DF/HCC Clinical Investigator Education Series and/or Research Education Series Powerpoint presentations from the last three years.

Tools

CTEO has designed a variety of easy to use tools to assist with study management and regulatory and DF/HCC requirements. Each template can be downloaded and customized to meet the specific needs of the study.

Tip Sheets

CTEO Tip Sheets are a collection of practical reference sheets bringing the concepts of good clinical practice to life.

29.5 In-services

CTEO staff is available to participate in conduct small group in-services and round table discussions addressing a variety of topics relating to study conduct, DF/HCC policy, and good clinical practice. These sessions are planned at a time and location convenient to the attendees. Requests for individual or departmental training sessions should be forwarded to the CTEO Education Coordinator at cteo@dfci.harvard.edu or 617-582-8480.