

PREFACE AND ACKNOWLEDGMENTS

In June 1996, the Dana-Farber Cancer Institute (DFCI) formalized its collaboration with Brigham and Women's Hospital (BWH) and the Massachusetts General Hospital (MGH) to establish the Dana-Farber/Partners Cancer Care (DF/PCC) system. This venture merged the three adult cancer care practices and provided the opportunity and impetus to form new collaborations in clinical research activities.

In 1999, Dana-Farber and its affiliates formed the Dana-Farber/Harvard Cancer Center (DF/HCC), a collaboration designed to bring seven Harvard-affiliated institutions together: Beth Israel Deaconess Medical Center (BIDMC), Brigham and Women's Hospital (BWH), Children's Hospital Boston (CHB), Dana-Farber Cancer Institute (DFCI), Massachusetts General Hospital (MGH), Harvard Medical School, and Harvard School of Public Health. This effort continues to be supported by the renewals of Dana-Farber's Comprehensive Cancer Center support grant from the National Cancer Institute (NCI) in October 2005. All adult oncology services, medicine, radiotherapy, and surgery are coordinated under a common management system.

As a result of this collaboration, DF/HCC is the largest cancer care provider in New England and is one of the largest single contributors to NCI-sponsored clinical research in the United States.

The Guide to Human Research Activities outlines the current practices and procedures involved in the human research process at the DF/HCC. The guide is directed toward staff who are or who will be involved with conducting human research trials: investigators, research nurses, project managers, study coordinators (SCs), and data managers, among other individuals involved in the research process. New fellows and data management staff may find the material particularly useful as they become acquainted with their roles.

The DF/HCC complies with all Federal regulations governing the conduct of research involving human subjects. For human subject review and approval purposes, the Office for Human Research Studies (OHRS) has independent authority and the ability to access and communicate with the most senior officials including the Chief Executive Officer (CEO), as appropriate.

Questions regarding the conduct of DF/HCC research may be forwarded to representatives in the Office for Human Research Studies (OHRS), the Quality Assurance Office for Clinical Trials (QACT), and the Clinical Trials Education Office (CTEO).

All DF/HCC institutions will follow the processes outlined in this manual for all oncology clinical trials involving DF/HCC subjects.

The text contained in this manual is revised as policies and procedures change.

Contributors:
Office for Human Research Studies (OHRS)
Quality Assurance Office for Clinical Trials (QACT)
Clinical Trials Education Office (CTEO)
Research Pharmacy
Research Nursing
Biostatistics Core
Biosafety Officers
Conflicts of Interest Officers