

# INTRODUCTION

The Dana-Farber/Harvard Cancer Center (DF/HCC) is one of the country's federally designated comprehensive cancer centers. As such, DF/HCC is responsible for all aspects of cancer care ranging from basic scientific research and research subject care (both pediatric and adult) to the training and education of future cancer specialists. DF/HCC also provides outreach programs to help educate laypersons and affiliated community hospitals about up-to-date cancer treatments.

At the core of the DF/HCC's responsibilities is the conduct of basic research. Because there is currently no known cure for many cancers, treatment relies on the advances of research. Many treatments at the DF/HCC are presented in the form of research protocols, otherwise known as clinical trials. Pertinent information also is obtained through non-clinical trials such as research involving specimens or data, community-based research or research involving the use of a questionnaire. This type of research also is conducted at DF/HCC.

This guide outlines the course of the clinical trial process from beginning to end and identifies the procedures for the various steps in the process. It will also address non-clinical trial research that makes up a large portion of the work done by investigators in the DF/HCC. The guide also describes what investigators need to know about their responsibilities, including subject registration policies, adverse event reporting, subject confidentiality, and informed consent.

Ultimately, the goal of this guide is to identify standards to ensure consistent and uniform research practices.