DF/HCC CCSG Protocol Review and Monitoring Requirements

As required by the Dana-Farber/Harvard Cancer Center (DF/HCC) National Cancer Institute (NCI) Cancer Center Support Grant (CCSG), DF/HCC conducts centralized protocol review and monitoring for all cancer-related hypothesis-driven clinical research studies undertaken by investigators at DF/HCC institutions. For the purposes of the CCSG, NCI defines clinical research as interventional and non-interventional patient-oriented research, epidemiological and behavioral research, and health services research. Patient-oriented research includes treatment, supportive care, prevention, diagnostic and screening studies, as well as research with human specimens collected by investigators through direct interaction with research subjects. NCI also expects that any human subjects research taking place at DF/HCC institutions that is funded by NCI, even if not directly cancer-related (e.g., tobacco use studies) be centrally monitored. DF/HCC convenes Scientific Review Committees (SRC) to oversee protocol review and monitoring of all cancer related clinical research as required under the CCSG.

SRC review is separate from and in addition to Institutional Review Board (IRB) review, which focuses on the protection of human subjects. DF/HCC institutions have agreed to rely on the Dana-Farber Cancer Institute (DFCI) IRB for ethical review of cancer-related clinical research. Some multi-institutional or externally sponsored studies rely on commercial or external single IRBs. DFCI has, in turn, agreed to rely on DF/HCC institutions for review of certain research as well. The DF/HCC institutions include:

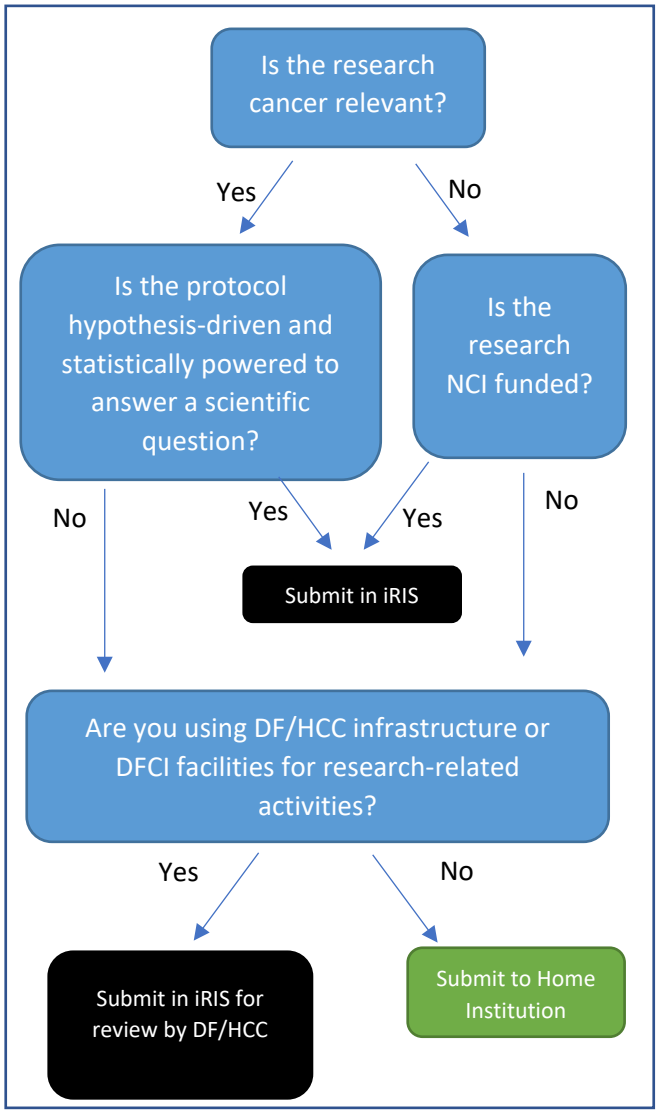
- Beth Israel Deaconess Medical Center (BIDMC)
- Boston Children's Hospital (BCH)
- Brigham and Women's Hospital (BWH)
- Dana-Farber Cancer Institute (DFCI)
- Massachusetts General Hospital (MGH)
- Harvard Medical School (HMS)
- Harvard School of Public Health (HSPH)

The DF/HCC Office for Human Research Studies (OHRS) is the office at DFCI that manages DF/HCC SRC review and DFCI IRB review, including reliance on external IRBs. All submissions to OHRS and DF/HCC are accomplished in the iRIS system.

Centralized data-safety monitoring (DSMC/DSMB) and auditing are part of the DF/HCC protocol review and monitoring system. The DF/HCC Office for Data Quality (ODQ) is the office at DFCI that manages the DF/HCC data safety monitoring and auditing.

Under the conditions of the CCSG, the NCI requires regular reporting of all DF/HCC research activities. For all research reviewed under the DF/HCC protocol review and monitoring system, reporting is managed by DF/HCC Research Informatics Office and ODQ. For research that is CCSG relevant but not reviewed under the DF/HCC protocol review and monitoring system, individual investigators may be responsible for providing protocol data to DF/HCC for inclusion in reports to the NCI.

To help determine what research requires submission to DF/HCC for scientific review and CCSG reporting, the following decision tree is provided as a guidance:



1. Is the research cancer relevant (e.g., specifically recruiting patients with cancer or asking cancer-relevant scientific questions including cancer screening, cancer prevention, cancer-related outcomes, or assessments of cancer risk)?

This may include interventional research, observational research involving cancer patients and/or healthy populations, as well as specimen-based research. See the following section for specific examples.

AND

Is the protocol hypothesis-driven and statistically powered to answer a scientific question?

Yes to both (DF/HCC) ***or*** No (next question)

2. Is the research funded by the NCI?

Yes (DF/HCC) ***or*** No (next question)

3. Does the research use DF/HCC infrastructure or DFCI facilities for research-related activities, causing Dana-Farber Cancer Institute to be engaged in human subject research? For non-cancer relevant research in which DFCI is engaged or DF/HCC infrastructure is used, submission to OHRS in iRIS for feasibility reviews may be required; review by the DFCI IRB is optional. Examples of DF/HCC infrastructure or DFCI facilities are listed below:

- DFCI Research Pharmacy Services
- DFCI Cell Manipulation Core Facilities (CMCF)*
- Electronic Forms Capture
- Data Safety and Monitoring
- Data Management
- Registration in OncCore or OncPro

Yes (DF/HCC) ***or*** No (next question)

**Non-cancer research that utilizes CMCF needs to be evaluated by OHRS on a case-by-case basis.*

4. If no to all of the above, the study may be submitted to the investigator's home institution for appropriate review and approval.

IRB Offices and Contacts for Questions:

Beth Israel Deaconess Medical Center - Committee on Clinical Investigation (IRB)
Contacts: Andrea Collins / Wendy Moy
Boston Children's Hospital Institutional Review Board
Contacts: Susan Kornetsky
Dana-Farber Cancer Institute - Office for Human Research Studies (OHRS)
Contacts: OHRS@dfci.harvard.edu Lara Sloboda / Caroline Kokulis / Jeffrey Meyerhardt, M.D.
Mass General Brigham IRB
Contacts: Martha Jones

What Research is Considered Cancer Relevant?

The following table is intended to help clarify certain types of cancer related research studies and the appropriate review process. Research that is submitted to DF/HCC may rely on an external IRB for ethical review in some cases, but a full submission of the research to OHRS is still required for scientific review and CCSG reporting.

Investigators should seek guidance from their institutional IRB office before completing application forms if there is any uncertainty about the most appropriate review process for a specific study.

Research Involving	Required to Submit To
Chemotherapeutic drugs or immunotherapy to treat malignant tumors or used to treat the following nonmalignant tumors: Meningiomas, Schwannomas, Neurofibromas, Pancreatic cysts or Neuroendocrine pancreatic tumors.	Submit to DF/HCC through the iRIS system – For review by DFCI IRB or reliance on external IRB *For DFCI engaged non-cancer research, submission is required for the relevant feasibility review, but IRB review may be at home institution
Cryotherapy or radioablation of malignant tumors	
Novel surgical approaches to cancer therapy	
Pain management OR alternative medicine approaches to cancer therapy	
Radiological diagnostic techniques directed at patients with cancer or follow-up of cancer therapy	
Cancer risk, screening or prevention	
Questionnaires / surveys directed at patients with cancer	
Health services research / cost effectiveness analysis	
Mixed Patient Populations including a subset of cancer patients where cancer-relevant populations are specifically recruited and/or cancer-relevant scientific questions are researched	
*Greater than Minimal Risk, Non-Malignant Hematology when Dana-Farber Cancer Institute is engaged in research	

Research Involving	May be submitted to
Treatment of the following **nonmalignant tumors without chemotherapy or immunotherapy**: Meningiomas, Schwannomas, Neurofibromas, Pancreatic cysts or Neuroendocrine pancreatic tumors.	Principal Investigator's Institution
Treatment of osteomas	
Treatment of warts / localized papilloma	
Mixed Patient Populations where the inclusion of cancer-related populations is incidental	
Nursing practice and/or quality improvement projects related to cancer care	
Collection of blood/tissue for genetic testing directed at patients with cancer when Dana-Farber Cancer Institute is not engaged in research	
Health / medical records of patients with cancer when Dana-Farber Cancer Institute is not engaged in research	
Tissue banks and/or sample/data repositories without scientific objectives	
Infectious Disease Research	
Humanitarian Use Device / Humanitarian Device Exemptions for clinical treatment of patients	

What if my research was not submitted to the DF/HCC initially?

National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) relevant studies conducted at a DF/HCC site but not reviewed, submitted to/or tracked by the DF/HCC Office for Human Research Studies (OHRS) may require reporting by the principal investigator to OHRS for the purposes of CCSG reporting. This reporting requirement is determined by the NCI and the DF/HCC Office for Data Quality (ODQ).

Examples of required data include:

- *Study Identifier (e.g., Lead Org, NCI, CTEP, or DCP Protocol ID Number)*
- *Subject Study Identifier*
- *Study Site Identifier*
- *Zip Code (if US)*
- *Country of Residence (if not US)*
- *Patient's Date of Birth MM/YYYY*
- *Gender of a Person*
- *Ethnicity*
- *Subject Registration Date*
- *Subject Disease Code*
- *Race*

The DF/HCC Office for Data Quality (ODQ) will reach out to the principal investigator to request required study level data as needed.