

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: Protocol Related Care for Study Subjects at a Non-DF/HCC Facility

SOP #: SM-502

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**Applicable Regulations
& Guidelines:**

[FDA Information Sheets, October 1998: Use of Investigational Products When Subjects Enter a Second Institution](http://www.fda.gov/oc/ohrt/irbs/investigational.html)
(<http://www.fda.gov/oc/ohrt/irbs/investigational.html>)

[Engagement of Institutions in Research \(January 26, 1999\)](http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm)
(<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>)

Other References:

PM-412 Confidentiality of Industry Sponsored Research Protocols; PM-409 Regulatory Binder Management
[OHRs Information Sheet](#)

Responsible Personnel:

DF/HCC Principal Investigator (PI) or study staff designee

Policy Statement:

[Subjects who are eligible for DF/HCC protocols may not receive any procedures under the protocol at a non-DF/HCC facility, unless there is an appropriate \(1\) IRB approval at that site; or \(2\) the procedures fall under an exception as set forth by OHRP and FDA or other applicable regulatory agency. The PI is responsible for ensuring valid site IRB approval before allowing a subject to receive protocol related care at a non-DF/HCC facility.](#)

Procedure:

- 1) The PI or study staff designee must identify subjects who will receive portions of protocol related care at a non-DF/HCC facility.
- 2) The PI or study staff designee must obtain written sponsor approval before [contacting OHRs](#) or releasing a copy of the full protocol and/ or any other protocol related documents [to the non-DF/HCC facility.](#)
- 3) [The PI or study staff designee contact OHRs for a determination as to whether the if the procedures fall under an exception as set forth by OHRP and FDA. For example, laboratory testing \(CBC, Chem\) or radiological testing \(MRI, CT, X-ray\), where the test is done locally \(for commercial purposes\), but the results are forwarded to the study team for review. The OHRs correspondence must be filed in the DF/HCC Lead Site regulatory binder.](#)

- 4) Once OHRHS has determined whether or not the procedures fall under an OHRP/FDA exception, the following items must be sent by the PI or designee to the outside facility's treating physician prior to care:
 - a) a copy of the physician note outlining the section of the protocol that will be performed at the outside facility
 - b) a copy of the entire protocol and/or any protocol related documents
 - c) a copy of the signed consent document.
- 5) The PI or study staff designee must ensure IRB approval at the non-DF/HCC facility has been obtained, if applicable, and the documentation has been filed in the DF/HCC Lead Site regulatory binder.
- 6) The PI or study staff designee is responsible for the collection of protocol data created at the outside facility.

Original Approval Date: CLINPOC 11/16/04

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Effective Date: 10/16/08