

Dear DF/HCC Research Community,

This email is to alert you of two new policies and two revised policies which have been approved and posted to the Clinical Research Support section of the DF/HCC website today:

NEW POLICIES

QA-716 Case Report Form (CRF) Data Submission Compliance for PI-Initiated Trials

QA-721 Policy for Routine Monitoring Visits by External sponsors

MINOR REVISIONS TO EXISTING POLICIES (refer to attached tracked changes documents)

QA-708 Monitoring Phase I Dose Escalation for PI-Initiated Protocols

QA-709 Monitoring Phase II Early Stopping Rules for PI-Initiated Protocols

To access this site from the Clinical Trials Portal, click on Clinical Research Support which is located just below OPRS on the Portal Menu. Next, click DF/HCC Clinical Research Policies and Procedures in the Quick Links box.

To access this site directly from the DF/HCC intranet: <http://www.dfhcc.harvard.edu/clinical-research-support/>

Please contact Jane or Nancy below with any questions.

Jane E. Russell, Quality Assurance Officer for Clinical Trials, (617) 632-3764

Nancy M. Antonino, Clinical Research Operations, (617) 632-5188

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

TITLE: Monitoring Phase I [Early Stopping Rule](#) [Dose Escalation](#) for ~~DF/HCC~~ PI-Initiated Protocols

SOP #: QA-708

Page: 1 of 1

**Applicable Regulations
& Guidelines:**

Other References: Protocol Documents
DF/HCC PI-Initiated Phase I Clinical Trials Dose Escalation Form

Responsible Personnel: DF/HCC Principal Investigator (PI) or Research Nurse, Quality Assurance Office for Clinical Trials (QACT) Protocol Registrars

Policy Statement: [The Overall](#) PI is responsible for assuring that the dose escalation schema is followed in phase I DF/HCC PI-initiated protocols.

Procedure:

- 1) The QACT notifies the PI and Research Nurse when the last of a cohort of subjects has been registered to a DF/HCC initiated protocol.
- 2) The Principal Investigator or Research Nurse verifies the significant toxicities noted in the prior dose levels and states the next dose level open to enrollment.
- 3) The PI or Research Nurse completes the “Phase I Dose Escalation Form” for PI-initiated protocols at the end of each cohort of subjects and also at the time of declaration of the Maximum Tolerated Dose (MTD). The form is located on the QACT website (www.dfhcc.harvard.edu/QACT/) under policies and procedures.
- 4) The PI or Research Nurse emails or faxes the form to the QACT (gcc@partners.org, 617-632-2295). If the Research Nurse submits the form, the PI must be copied on the email. Additional subjects will not be registered until the Phase I Dose Escalation Form is received and/or if the specified waiting period between and within cohorts has not been met.
- 5) The PI or designee must obtain DFCI Institutional Review Board (IRB) approval if additional subjects, cohorts or dose-levels need to be added.
- 6) The PI is responsible for notifying the co-investigators of the study status.

Original Approval Date: CLINPOC 11/16/04

Revision Dates: [5/14/08](#)

Effective Date: [5/14/08](#)

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

TITLE: Monitoring Phase II Early Stopping Rule for DF/HCC PI -Initiated Protocols	
SOP #: QA-709	Page: 1 of 1

**Applicable Regulations
& Guidelines:**

Other References: Protocol Documents
Phase II Early Stopping Rule Form

Responsible Personnel: DF/HCC Overall Principal Investigator (PI) or study staff designee, Quality Assurance Office for Clinical Trials (QACT) Protocol Registrars

Policy Statement: The Overall PI is responsible for assuring that early stopping rules are followed in phase II DF/HCC ~~PI~~-initiated protocols.

Procedure:

- 1) QACT notifies the Overall PI that the protocol has reached the accrual target at which the trial must be evaluated per the early stopping rule.
- 2) The Overall PI reviews data with study team to determine whether the protocol should remain open or close to further enrollment.
- 3) The Overall PI or study staff designee must complete the “Phase II Early Stopping Rule Form” for PI-Initiated protocols before the first subject is registered on the second stage of the protocol. The form is located on the QACT website (www.dfhcc.harvard.edu/QACT/) under policies and procedures.
- 4) The Overall PI or study staff designee will email or fax the form to the QACT (qcc@partners.org, 617-632-2295). When the study staff designee submits the form, the Overall PI must be copied on the email. Additional subjects will not be registered until the Phase II Early Stopping Rule Form is received.
- 5) The Overall PI or designee will notify all other investigators of the study status.
- 6) When the study is closed, the Overall PI or study staff designee must notify the IRB.

Original Approval Date: CLINPOC 11/16/04
Revision Dates: <u>5/14/08</u>
Effective Date: <u>5/14/08</u>