

# **Audit Alert**

## **DF/HCC Audit Program**

### **DF/HCC Initiated Multi-Center Trials: Informed Consent Documents for External Participating Sites**

*This alert is to give feedback from findings from our internal auditing program and from audits conducted by external groups (i.e. FDA, CALGB, RTOG etc.).*

Recent audits have identified incorrect or missing elements in the informed consent documents and/or HIPAA authorizations of external sites of participating in DF/HCC Initiated Multi-Center Trials. Specifically issues have been found in the areas of trial sponsorship, patient compensation regarding injury and authorization for the release of personal health information (PHI).

Please review the excerpt on informed consent documents from the DF/HCC SOP: PM-402 Conducting PI-initiated Multi-Center Trials:

#### Informed Consent

The Lead Site study team develops the model research consent document that must include a statement that data will be shared with the sponsor or its agents (which may include an outside CRO, medical monitor, Lead Site (DF/HCC), DSMB/DSMC and Lead Site's study team. The consent form must state that data shared with the Lead Site may include subject identifiers (name, date of birth, medical record number). The Overall PI or designee is responsible for obtaining copies of each site's IRB approved consent forms. Each consent form must be reviewed for compliance with the DF/HCC multi-center consent template.

If you are the Lead Site for a DF/HCC Initiated Multi-center Trial please ensure all of the external participating sites informed consent documents and/or authorization forms have been reviewed for compliance. Please use the links provided below for further information:

Guidance Document for DF/HCC Model Consent Language for Multi-Center Trials  
[http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/QACT/Multi-Center\\_Trials/DFHCC\\_Model\\_Consent\\_Language\\_for\\_Multi-Center\\_Trials.doc](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/QACT/Multi-Center_Trials/DFHCC_Model_Consent_Language_for_Multi-Center_Trials.doc)

DF/HCC SOP: PM-402: Conducting PI-initiated Multi-Center Trials  
[http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/QACT/Multi-Center\\_Trials/PM-402\\_Conducting\\_PI-Initiated\\_Multi-center\\_Trials\\_at\\_DFHCC\\_02\\_1\\_.pdf](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/QACT/Multi-Center_Trials/PM-402_Conducting_PI-Initiated_Multi-center_Trials_at_DFHCC_02_1_.pdf)

For more information on conducting DF/HCC initiated multi-center trials please refer to the multi-center trials section of the QACT website  
<http://www.dfhcc.harvard.edu/clinical-research-support/quality-assurance-office-for-clinical-trials-qact/multi-center-trials/>

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