

Dear DF/HCC Research Community,

It was brought to the attention of CLINPOC that there are sites external to DF/HCC which allow nurses to obtain written consent from study participants consenting to risk treatment protocols. CLINPOC has decided that external sites must comply to our DF/HCC policy requiring that only physicians may obtain written consent for risk treatment protocols.

The following policies have been updated and posted to the **Clinical Research Unit** website:

PM-402 Conducting PI-Initiated Multi-center Trials

QA-712 Subject Protocol Registration

SM-501 Obtaining Informed Consent in Human Research Studies

Documents for Multi-center Trials on the **QACT Website**:

Multi-center DSMP has been updated.

Instructions for Modifying the Multi-center DSMP is a new document to assist staff with preparing the protocol specific Multi-center DSMP.

Information for External Sites is a new document that has been added and should be provided to each external site participating in a PI-initiated Multi-center trial.

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.

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