

Dear DF/HCC Research Community,

The following policy with an effective date of 4/10/08:

PM-409 Regulatory Binder Management:

The policy statement was revised to delete the sentence regarding duplicate regulatory binders. This statement has caused some confusion. Instead, the policy statement now begins with the sentence "There is only one master regulatory binder." Study coordinator replaced "CRA/CRC" throughout the policy.

Checklists:

The Lead Site and Non-Lead Site Regulatory Binder Checklists have also been updated and posted. The revisions are the result of a lot of helpful feedback and questions from the study teams and the QACT internal auditors. Please note that these checklists are not intended for social/behavioral research studies. Separate checklists for those studies are currently under development.

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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