

The following policies have undergone minor administrative updates and have been posted to the **Clinical Research Support** website:

PM-411 Protocol Specific FDA 1572 Form

Procedure # 3c. Block 6: A new sentence was inserted into this paragraph: "Under certain circumstances fellows may be listed on the 1572 form. Contact your institutional cancer clinical trials office for guidance." Procedure # 3e has been revised by changing "must" to "should".

SM-502 Protocol Related Care for Study Subjects at a Non-DF/HCC Facility

The Applicable Regulations and Guidelines and References have been updated at the top of the policy and under procedure # 3.

QA-712 Subject Protocol Registration

Procedure # 3 a was revised to state "QACT director or designee". Procedure # 6 was revised to include " c) Wait for registration confirmation prior to initiating study administration." Procedure # 11 was revised to include "Protocol registration and confirmation is required before protocol orders can be written." QACT operational language under # 11 and # 13 has been deleted from the policy since it appears in other QACT documentation.

QA-713 Centralized National Cancer Institute (NCI) Annual Investigator Registration

Procedure # 4 was rewritten to state "DF/HCC study teams should contact the CTEO with the names of new Investigators requiring registration." Procedures # 5 and # 6 were deleted. Procedure # 6 is already addressed in the consenting policies.

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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