

## Guidance on Protocol Related Care for Study Subjects at a Non-DF/HCC Facility

As stated in DF/HCC SOP SM-502, subjects who are eligible for DF/HCC protocols may not receive any procedures under the protocol at a non-DF/HCC facility, unless there is an appropriate (1) IRB approval at that site; or (2) the procedures fall under an exception as set forth by OHRP and FDA or other applicable regulatory agency.

Please obtain prospective IRB approval, by submitting one of the following to OHRS for processing:

**New Project Application Form:** If it is anticipated that subjects will receive protocol related care at non-DF/HCC facilities at the time a new protocol is submitted for initial review, please make sure to note this in the new project application form as requested in response to the relevant questions.

**Protocol Deviation Report Form:** If, after the protocol has been approved by the IRB, it is anticipated that protocol related care for subjects will be conducted at non-DF/HCC facilities, please submit a deviation request to OHRS. The request should describe what care will be conducted at the non-DF/HCC facilities as well as include sponsor approval.