Dana-Farber/Harvard Cancer Center (DF/HCC) Clinical Trial Operational Feasibility Form

DF/HCC Policy and Operation Library: https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library/dfhcc-policy-and-operation-library/

Instructions for Sponsor: The purpose of this form is to identify any key policy/procedure conflicts between the sponsor and study site upfront. Please review each of the line items below and indicate "Agree" or "Further Discussion." If you select "Further Discussion," this will lead to further follow-up questions during the feasibility process after the study is submitted. If there are questions that are not applicable to the study, you may leave blank or write N/A.

THIS FORM SHOULD BE COMPLETED AND SUBMITTED BY SPONSOR TO STUDY TEAMS AT DF/HCC SITES

Standard Feasibility Conditions	Agree	Further Discussion
1. Please confirm review of DF/HCC site's institutional policies for dosing adjustment standards:		
a. Beth Israel Deaconess Medical Center recalculates dose for 10% changes in weight.		
b. Boston Children's Hospital recalculates dose for 10% changes in weight and/or BSA.		
c. Brigham and Women's Hospital recalculates dose for a discrepancy greater than 5% of the ordered chemotherapy dose.		
d. Dana-Farber Cancer Institute Adult and Pediatric outpatient recalculates dose for greater than 10% changes in weight and/or BSA.		
e. Massachusetts General Hospital recalculates dose if weight causes a greater than 10% change in dose.		
2. DF/HCC will use Dubois formula for all medications that require BSA dosing.		
3. DF/HCC sites may perform drug allocation the day prior to administration.		
4. DF/HCC will perform a U/A for urine testing over dipsticks as DF/HCC sites do not support the use of urine dipsticks.		
5. DF/HCC may use Fredericia formula to correct QTc intervals on ECGs.		
6. ***Note:*** If your protocol does not involve research oral drug, please disregard. If the sponsor is not supplying a drug diary, the DF/HCC drug diary template will be used.		
a. **If the sponsor will supply a drug diary template, please confirm review of DF/HCC policy INV 103 to assure diary will fall in line with our policy instructions.**		
7. Tracked versions and clean versions of protocol amendment documents will be sent to study team (i.e., pharmacy manuals, protocol version updates) at start up and with amendments.		

Instructions for Sponsor: Please review each of the line items below and select "Acknowledge." These are standard DF/HCC procedures that cannot be negotiated.

Standard Feasibility Conditions Continued	Acknowledge
8. DF/HCC sites will only use institutional forms for temperature logs and drug accountability logs.	
9. DF/HCC sites will only use institutional forms for temperature excursion except in cases where the sponsor requires temperature excursions to be reported in an electronic system.	
10. DF/HCC sites will only use institutional forms for drug destruction.	
Note: If needed, sponsor can request forms from site study team again after the completion of this form.	

To be completed by sponsor representative:

Sponsor Study #: _____

Study Sponsor or Designee: _____

Name of Sponsor(s) Designee/Contact Completing the Form: _____

Signature of Sponsor(s) Designee/Contact Completing the Form: _____

Date: _____