April 20, 2016

DFHCC Consortium Guidance
Summarized by the Clinical Investigations Leadership Committee and approved by the Clinical Sciences Coordinating Committee

1. As a consortium, we should strive to make all protocols available to all members and patients of DFHCC, should they wish to participate.

2. Sponsors should be encouraged to open a given clinical trial at all institutions within DFHCC.

3. Exceptions to this can be considered if the following conditions are recognized:

A) The study is open at 2 or more centers other than DFHCC, enrollment is competitive, and the study has a "run in" phase (or dose escalation phase for a phase I study) involving a limited number of patients that will be accrued within the DFHCC institutions (e.g., less than or equal to 10) that makes it more efficient to be conducted at only one institution as opposed to broadly throughout DFHCC.

B) For a given trial, such a restriction is agreed upon within the disease program (or phase I group), represented by relevant consortium members (e.g., BIDMC, Children's, DFCI, MGH, etc).

C) Documentation of items A and B above should be provided at the time of protocol submission, so that this information can be reviewed by the SRC and IRB.

D) Once the "run in" phase is completed, if the study proceeds to an expansion phase (either in a phase I setting, or a phase I-II transition), it is expected that the study will be made broadly available throughout DFHCC at that time. This expectation should be explicitly addressed with the sponsor prior to beginning the study (i.e, at the "run in" phase).

4. Institutions that are committing to opening a trial are expected to accrue to that trial. Accrual to these types of trials will be tracked by institution and disease center within institutions and consistent inability to accrue may lead to these types of trials not being opened within that institution’s disease center in the future.

5. Consistent evidence of poor performance in trial conduct (e.g. regulatory, good clinical practice, timely data submission, etc.) within an institution’s disease center may lead to these types of trials not being opened within that institution’s disease center in the future, until poor performance has been addressed.