Frequently Asked Questions for DF/HCC Investigators:

NIH sIRB Requirement for Multi-Center Research

1. Whom does this apply to?

If all the following apply then an sIRB is required to be utilized for the review of research:

1. The research involves non-exempt human subjects; and
2. The research involves funding from NIH; and
3. The research involves more than one site.

2. What does using a sIRB mean for the DF/HCC Overall Principal Investigator?

With this new NIH Policy, the DF/HCC Overall PI of a multi-site clinical trial assumes new responsibilities relating to the logistics of sIRB review including, but not limited to:

1. Selecting an IRB to serve as the sIRB;
2. Confirming that all participating sites are willing to rely on that selected sIRB;
3. Developing a communication plan between the lead and participating sites and the sIRB;
4. Developing a budget to cover the costs of the sIRB.

3. If you are the DF/HCC Overall PI, what do you have to include in the grant application?

The DF/HCC Overall PI must include the following information in the proposal:

1. Identification of the IRB that will serve as the sIRB of record;
2. Confirmation that all sites are willing to rely on that sIRB of record and sign a reliance agreement that will include a communication plan;
3. Identification of where records of the reliance agreements will be maintained; and
4. A budget for sIRB review

4. Will there be a fee or other costs for the use of a sIRB?

Yes. A budget will have to be developed and included in the grant application. Note that this budget must be developed for the duration of the grant (e.g. 5 years).

- If an independent sIRB is selected, the DF/HCC Overall PI should work with that Independent IRB to create an estimated budget.

- If the DFCI IRB agrees to serve as the sIRB, the PI must contact OHRS to develop a budget following the Request to Rely Process.
- If an sIRB at another academic medical center, university or private institution is selected, the DF/HCC Overall PI should contact that sIRB to develop a budget.

5. What if the grant budget underestimates the actual cost of sIRB review and budgeted funds are insufficient?

The DF/HCC Overall PI is responsible for covering all sIRB costs. If the original NIH award does not include sufficient funds, the PI may apply to the NIH for additional funds. If these funds are not provided, the PI must cover the cost from department funds.

6. Which IRBs can serve as the sIRB?

The following minimum criteria are required DF/HCC sites to rely on an External sIRB:

1. Current approved FWA, IORG and IRB numbers with OHRP;
2. Current AAHRPP Accreditation;
3. Qualification and Experience in the review of oncology research, such as a designated NCI Comprehensive Cancer Center; **and**
4. No recent FDA Warning Letters.

Please refer to the OHRS Guidance on Single IRB Review Process for more information about who the DFCI IRB may agree to rely upon: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/IS_-_Operations_-_Guidance_for_Single_IRB_Review_Process.pdf

7. Can I use the DFCI IRB as the sIRB of Record for My Research?

No, with limited exceptions. For more information, please read the OHRS Information Sheet on the DF/HCC and the NIH sIRB Requirement: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/IS_-_Resource_-_DFHCC_and_the_NIH_sIRB_Requirement.doc

8. If the DFCI IRB will not serve as the sIRB of Record, how do I request to Rely on an Outside sIRB?

All Investigators must follow the "Request to Rely" process for requesting use of an external IRB or requesting that DFCI serve as the single IRB. Please submit to OHRS a Request to Rely on a Single IRB located here: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/01_-_Forms/SIRB_-_Notice_of_Request_to_Initiate_Reliance_Agreement.doc

9. How do I consult with OHRS about using the DFCI IRB?
If you determine from the OHRS Information Sheet that the DFCI IRB may agree to serve as the IRB of Record, please submit a Request to Rely form to OHRS for consideration.
Select the Step 2 Tab: Requesting to Rely on a Single IRB.
Open and complete the "Notice of Request to Rely on a Single IRB" Form linked here:
http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/01_-_Forms/SIRB_-_Request_to_Rely_on_Single_IRB.doc

10. How long will it take to receive a response from OHRS regarding the request to rely?
OHRS staff will review the "Request to Rely" after submission and respond within **2 business days**. Please email the OHRS sIRB Email box upon submission to OHRS at OHRSCentral_IRB@dfci.harvard.edu.

11. How long will it take OHRS to develop a sIRB Budget?
If the DFCI IRB agrees to serve as the sIRB of Record for the research, it may take up to an additional **15 business days** to determine and provide the DFCI sIRB budget.

12. What does this policy mean when DF/HCC is not the Lead Institution?

DF/HCC Investigators who are at participating sites in an NIH-funded multi-site study relying on a sIRB must be aware of their responsibilities under this policy. Participating site responsibilities include, but are not limited to:

1. Consulting with OHRS regarding willingness to rely on the selected sIRB via the Request to Rely process;
2. Communicating OHRS's $1500 fee for management of ancillary DF/HCC reviews and other organizational responsibilities;
3. Following OHRS Policies and Procedures and Guidance Documents for relying on a sIRB;
4. Awareness of the communication process as determined by the Overall Lead PI; **and**
5. Working with the selected sIRB to provide reference materials (local context) and regulatory submissions as requested.

13. All other Questions can be directed to the DFCI OHRS sIRB email box at:
OHRSCentral_IRB@dfci.harvard.edu