Frequently Asked Questions for DF/HCC Investigators:

NIH Single IRB (sIRB) Requirement for Multi-Center Research

1. Whom does the NIH sIRB mandate apply to?

If all the following apply, then it is required to rely on a single IRB.

- The research involves non-exempt human subjects;
- The research involves funding from NIH
- The research involves more than one site; and
- The request is to only cover domestic research.

2. Which IRBs can serve as the IRB of Record?

The following criteria will be considered when deciding to allow a study to rely on an external IRB:

- Current approved FWA, IORG and IRB numbers with OHRP;
- Current AAHRPP Accreditation;
- Qualification and Experience in the review of oncology research, such as a designated NCI Comprehensive Cancer Center;
- Requirement by funding source or agency to use a sIRB; **and**
- No recent FDA Warning Letters within the past five (5) years.

3. What responsibilities does the Core site Principal Investigator (PI) maintain?

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

- Selecting an IRB to serve as the sIRB;
- Confirming that all participating sites are willing to rely on that selected sIRB (see FAQ 4 for more information);
- Developing a communication plan between the lead and participating sites and the sIRB;
- Developing a budget to cover the costs of the sIRB.

4. How should I communicate that other DF/HCC or non-DF/HCC sites are willing to rely on the selected sIRB?

Research team communication with other research sites is imperative to ensure a smooth review process. OHRS highly recommends that research teams communicate with other DF/HCC and non-DF/HCC sites regularly throughout the review process.

Once the research team and/or sponsor has agreed to rely on a sIRB and the Request to Rely has been submitted, the core research team will begin communicating with other DF/HCC participating sites. This will ensure that all of DF/HCC participating sites are communicating with each other to decrease duplicative efforts when relying on a sIRB. The core DF/HCC research team should gather the following information from non-core sites: name and contact information of the PI and

research manager. If DF/HCC research teams are unsure of who should be classified as the core research team, OHRS recommends that the research teams discuss who will be primarily submitting IRB applications in iRIS. For example, if DFCI will be submitting the New Project Application and Progress Reports, then OHRS would classify this research team as a core research team. If the research teams require assistance with either determining the core research team or additional information on how to communicate with other DF/HCC participating sites, please contact the OHRS Central IRB inbox (OHRSCentral_IRB@dfci.harvard.edu) for guidance.

In addition, the core research team should ensure that all non-DF/HCC participating sites have agreed to rely on the same IRB of record. There may be substantial delays in the review process when participating sites are not in agreement of who will be the IRB of record,

5. What additional responsibilities are there for the Core Site PI when DFCI is not the IRB or Record?

DF/HCC Investigators who are participating in NIH-funded multi-site research must be aware of their responsibilities under this policy.

- Participating site responsibilities include, but are not limited to: Consulting with OHRS regarding willingness to rely on the IRB of record via the Request to Rely process;
- Following OHRS policies and procedures and guidance documents for relying on a sIRB;
- Awareness of the communication process as determined by the DF/HCC Core PI; **and**
- Working with the selected sIRB to provide reference materials (local context) and regulatory submissions as requested.

6. Do I have to submit a Request to Rely for research that relies on one of the consortium site's IRBs (e.g., BCH, BIDMC, MGB, HSPH, HMS)?

Yes. A Request to Rely submission is required for all studies that rely on an external IRB, excluding the NCI CIRB and the NMDP IRB.

7. Can I use the DFCI IRB as the IRB of Record for my research?

Yes, under limited circumstances. For more information, please contact the OHRS Central IRB inbox, OHRSCentral_IRB@dfci.harvard.edu.

8. How many sites are allowed to rely on the DFCI IRB?

It depends. This answer will vary depending on the type of research and how other sites consider themselves engaged in the research. Please reach out to the DFCI OHRS Central IRB inbox at OHRSCentral_IRB@dfci.harvard.edu for additional communication prior to submitting the Request to Rely.

9. If the DFCI IRB will not be serving as the IRB of Record, how do I request to rely on an external IRB?

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. If you are unclear on the Request to Rely process, please contact the OHRS Central IRB inbox (OHRSCentral_IRB@dfci.harvard.edu).

10. For external IRBs that do not require a Request to Rely, how should I proceed with submitting my research?

If a Request to Rely is not required, DF/HCC study teams should move forward with submitting the New Project Application. Research teams should make sure to clarify in the NPA which IRB of record will be used. Please note that this does not negate the need for SRC, Feasibility, and Ancillary Reviews.

11. How do external sites receive the DFCI IRB approved documents?

The DF/HCC Research Team is responsible for disseminating the DFCI IRB approved documents to relying sites.

12. How long will it take to receive a response from OHRS regarding the request to rely?

It depends. The length of the Request to Rely process varies depending on which DF/HCC sites consider themselves engaged in the research.

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

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

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

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

The DF/HCC Core 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.

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

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

All other questions regarding the use of a sIRB can be directed to the DFCI OHRS Central IRB inbox at:
OHRSCentral_IRB@dfci.harvard.edu.