Frequently Asked Questions for Relying on the Western Copernicus Group IRB (WCG IRB):

1. **This is my first WCG IRB study, is it possible to communicate with OHRS to determine how I should proceed?**

   Yes. Please contact the OHRS general inbox (OHRS@dfci.harvard.edu) and OHRS Central IRB (OHRSCentral_IRB@dfci.harvard.edu) to set up an appointment to review the WCG IRB submission process. We are happy to help in any way possible.

Initial Project Set-Up

2. **Should I submit a Request to Rely for studies that rely on the WCG IRB?**

   Yes. OHRS requires that the research team submit a Request to Rely submission for research studies for which the research team would like WCG IRB to serve as the IRB of record for their research.

3. **I have an industry-sponsored Phase I trial that would like to utilize the WCG IRB, how should I communicate this with OHRS?**

   In most cases, WCG will serve as the IRB of record for only Phase II and Phase III trials. The research team should submit a Request to Rely. OHRS will evaluate the request to rely and communicate with any other DF/HCC sites to determine if the Phase I trial should cede IRB oversight to the WCG IRB or remain internally. It is important to note that Phase I trials are evaluated on a case-by-case basis.

Submitting to the WCG IRB

4. **When I am ready to apply to the WCG IRB, where should I submit an Initial Submission or any change in research documents?**

   The research team or Sponsor must submit any research documents in the WCG IRB system, Connexus. For more information on how to create a Connexus account, please review the Commercial IRB section on the single IRB page on the OHRS website.

5. **Who should submit the Initial Submission to the WCG IRB in Connexus?**

   The research team and sponsor should communicate to determine who will submit the Initial Submission to the WCG IRB. When DF/HCC participating sites are relying on the WCG IRB, the Initial Submission should not be submitted until the research team has been provided with the DFCI SRC Approval Memo.

6. **Does each DF/HCC participating site need to submit their own Initial Submission the WCG IRB?**

   Yes. When relying on an external IRB the consortium sites act as individual entities. OHRS highly recommends that the research teams of the different DF/HCC participating sites should submit the Initial Submission simultaneously to ensure that the different Initial Submission submissions are being reviewed by the WCG IRB concurrently.

7. **How should multiple DF/HCC participating sites notify the WCG IRB that the research will be opened at all the sites in the consortium?**

   When submitting the Initial Submission, the research team should include the following statement in the comments section at the end of the Initial Submission. Please make sure to only include the sites that are involved in the research:

   This study is part of the DFHCC consortium and the Boston Children's Hospital [PI: Name of PI], Beth Israel Deaconess Hospital [PI: Name of PI], Brigham and Women's Hospital [PI: Name of PI], Dana-Farber Cancer Institute [PI: Name of PI], and Massachusetts General Hospital [PI: Name of PI], will be participating in this study.

8. **If I have a high priority submission that has been approved by the WCG IRB, whom should I contact to get the submission moved through iRIS?**

   Please contact the OHRS Central IRB inbox (OHRSCentral_IRB@dfci.harvard.edu) and the general OHRS inbox (OHRS@dfci.harvard.edu). It is important to note that high priority submissions are those that would impact the participants willingness to continue research interventions or impact their safety (e.g., increase in serious adverse events, increase in death due to research interventions).

Creating Consent Documents

9. **What DF/HCC Local Context Language needs to be included in the consent form?**

   The WCG IRB will insert the DF/HCC Local Context Language into the consent form prior to their review and approval. The Local Context Language can be found on the OHRS website under the following title, WCG IRB Local Context Language.

10. **How should the research team format the consent form when there are more than two DF/HCC participating sites?**

    The research team must list the core principal investigator on the first page of the consent form as shown below:

DF/HCC Principal Research Doctor / Institution: [Insert Name of **CORE PI** at the DFHCC]

On the second page of the consent form, the research team must include the contact information for all of the site principal investigators, for example:

Dana-Farber Cancer Institute

Investigator: [Name of Investigator with credentials, (e.g. Jane Do, MD, PhD]
[Insert Address of Investigator]

Study-Related Phone Number(s): [insert study-specific # for PI] 24-hour contact: [insert 24-hour contact #]

If the research team requires any additional information regarding the WCG consent form, please refer to the WCG IRB Local Context Language document regarding how to format the consent form when more than two (2) DF/HCC participating sites are engaged in research that relies on the WCG IRB.

Communicating with the DFCI IRB

11. How soon after the WCG IRB has reviewed and approved a change in the study should it be submitted to the DFCI IRB?

The research team should submit WCG IRB reviewed and approved document as soon as possible. This will ensure that there is minimal delay to activation and that study teams can implement the changes as soon as possible.

12. I received a comment from OHRS regarding a Certificate of Action, what is this referring to?

The Certificate of Action is the WCG IRB's version on an IRB Approval Memo.

13. The New Project Application is pending activation and I have an urgent Amendment that needs to be submitted. How should I proceed with getting the Amendment processed by the DFCI IRB?

Please contact the DFCI Navigator Team (DFHCCiRISNavigator@dfci.harvard.edu) to determine if the amendment can be submitted while the NPA is being activated.

14. How does a research team know when a study should be placed on hold while the submission is pending activation?

If a submission would impact the participants willingness to continue their participation in the research, then the study should be placed on hold, as an example, when additional information impacts participant's safety. If the research team is unclear on whether a hold should be placed, please contact the OHRS general inbox (OHRS@dfci.harvard.edu) and OHRS Central IRB inbox (OHRSCentral_IRB@dfci.harvard.edu).

Conducting Research Approved by the WCG IRB

15. Once the study has received WCG IRB review and approval, how does the research team navigate the use of the DFCI IRB policies and procedures?

After the research team has received the WCG IRB approval for the study specific documents, the research team may then begin to utilize the DFCI IRB policies and procedures (e.g., CON-100). It is important to note that the DFCI IRB cannot undue any determinations that have been made by the WCG IRB (e.g., reconsent language, IRB expiration date). There will be times when the DFCI and WCG IRB policies and procedures will need to be used in tandem (i.e., reporting of adverse events, see FAQ 17).

16. The WCG IRB has not approved the Continuing Review submission and I received a 60-day notification of expiration from OnCore. Should I submit the Progress Report in iRIS with the previously approved Certificate of Action memo from the WCG IRB?

No. OHRS expiration dates are based on the expiration date provided by the IRB of record. OHRS requires a current WCG IRB issued Certificate of Action that will extend the IRB approval period beyond the current expiration date. If the research is within 10 days of the expiration date, please contact the OHRS Central IRB inbox (OHRSCentral_IRB@dfci.harvard.edu) to indicate when the Progress Report will be submitted to ensure that the submission is prioritized.

17. Should I submit an Alert Page to the WCG IRB for review and approval?

No. If the Alert Page includes information that was provided on a Sponsor Clarification Memo and the WCG IRB has reviewed and approved the Sponsor Clarification Memo then the research team does not need to submit the Alert Page to the WCG IRB for review and approval. If the changes to the Alert Page have been requested during feasibility review, please provide the Study Chair approval for the revisions that have been made to the Alert Page.

18. Should a participant be notified if there is an amendment that has not been activated and includes revisions to the consent form?

It depends. If there are significant changes in the risks that would impact participant safety, then the research team should verbally notify the participant of these changes. If the consent form has been revised to update formatting errors, the participants do not need to be notified. OHRS is always available to advise should this be unclear. Please contact the OHRS general inbox (OHRS@dfci.harvard.edu) and OHRS Central IRB inbox (OHRSCentral_IRB@dfci.harvard.edu) with any questions.

19. How should events be reported to the WCG IRB and DFCI IRB?

The research team will need to understand the reporting requirements for both the WCG and DFCI IRBs. Research teams should confirm with the WCG IRB whether an event will need to be reported. If the event has been reported to the WCG IRB, the research team will also need to report the event to the DFCI IRB when it meets the criteria for an event based on the DFCI Event policy.

20. How can I convert a WCG IRB study to a study that relies on the DFCI IRB?

The DFCI IRB does not have a policy on utilizing the DFCI IRB when the study has been previously reviewed and approved by the WCG IRB. Generally, the DFCI IRB does not serve as a single IRB for multi-site clinical trials.