



Advarra as the IRB of Record

The following guidance is intended to give an overview of the process when DF/HCC sites rely on the Advarra IRB. When relying on an external IRB the consortium sites act as individual entities. Each DF/HCC site conducting research with a separate Principal Investigator will submit to Advarra using a separate Investigator Application.

As with other single IRB studies, research teams should submit a Request to Rely in iRIS. This submission should list each of the DF/HCC sites that will be involved in the research study, as well as whether any DF/HCC sites will be involved under the joint venture.

The Request to Rely Outcome Letter will list all the involved DF/HCC sites, as well as the Core Site PI and Subsite PIs (if included).

Submitting to the Advarra IRB with multiple DF/HCC with Separate Site Principal Investigators

If multiple PIs will be included in the initial submission:

- An Investigator Application will need to be completed for each PI. The Investigator Applications would need to be submitted at the same time so they can move through the Advarra system together.
 - The DF/HCC research team is responsible for amending the Sponsor or CRO consent template. The consent form template should be updated to include the DF/HCC required template language outlined in the [DFHCC Local Context Information](#) form. In addition to tracking any institutionally required language, the consent form should also list all other DF/HCC investigators and locations.
 - The Core Site PI should include the tracked consent with their initial submission of their Investigator Application.
 - **Please note:** If the other DF/HCC investigators will not be submitting at this time, they should not be included in the ICF. Instructions for that scenario are below.
 - After submitting their Investigator Application(s), the Subsite PI(s) should send a Contact IRB message that states “This study is part of the DFHCC consortium. **{Primary Investigator Name}** is the primary PI for the DF/HCC Consortium and will submit a separate Investigator Application including a tracked consent form to include PI **{Subsite PI Name}** and **{Site Name}**. No ICF should be released for this Investigator Application.”
 - Upon approval, Advarra will issue
 - a separate approval letter for each DF/HCC site.
 - only one consent form to the Core-Site PI.
 - Please submit each approval letter and the approved consent form in iRIS for acknowledgment.

If an additional DF/HCC site will be added to the protocol after the initial submission:

- An Investigator Application will need to be completed for each subsite PI.
 - After submitting their Investigator Application(s), the subsite PI(s) should send a Contact IRB message that states “This study is part of the DFHCC consortium. **{Primary Investigator Name}** is the primary PI for the DF/HCC Consortium and will submit an ICF



MOD to include PI {Subsite PI Name} and {Site Name} on that PI's ICF. No ICF should be released for this Investigator Application."

- After the Subsite PI submits their Investigator Application, the Core Site PI will need to take their currently approved ICF(s), update the list of investigators including the Subsite PI name and location, and submit an ICF MOD in CIRBI.

DF/HCC study teams should proactively communicate with their Sponsors/CROs regarding this set-up and DF/HCC's policy regarding a single ICF to help mitigate questions or confusion.

After initial approval details:

- As each PI will fall under their own SSU (Investigator Application), each will receive separate approval for any study-wide modifications or submissions.
- Each PI will be responsible for submitting their own site-level submissions, such as Continuing Review, any site-specific modifications (e.g., change in PI, change in research location, etc.), and any Prompt Reporting Events.

Submitting to the Advarra IRB when BWH, BCH, or DFCI are Listed Under the Joint Venture

When a DF/HCC institution is involved in the research under the joint venture, an Investigator Application should be submitted only for the DF/HCC site associated with the Core-Site PI. The Investigator Application should indicate which other DF/HCC sites are involved in the research under the same site PI.

- As an example, if DFCI is the Core Site and BWH is included in the joint venture, only DFCI will have to submit an Investigator Application, and BWH should be included as an involved site.
- The Consent Form should only list the Core-Site PI on the front page, but list the Core site and joint venture site in the contact information.