DF/HCC
DANA-FARBER / HARVARD CANCER CENTER

Pre and Post Submission Checklist

The tasks below are not handled within iRIS but must completed outside of the system to ensure coordination and communication within DF/HCC.

Pre-Submission:

Complete these tasks prior to submitting in IRIS.

- ☐ Communicate with DF/HCC Subsites
  - New Protocols: Share new protocols with other DF/HCC institutions and confirm their interest in participating prior to submission. If other DF/HCC sites are not participating, be prepared to indicate why when you make the submission. Notify all participating DF/HCC sites prior to making a submission and distribute updated documents in advance.
  - Amendments: Notify all participating DF/HCC sites prior to making a submission and distribute updated documents in advance.
- ☐ Notify Contracts, Budgets and/or Grants Offices
  - New Protocols: Provide the protocol, draft agreement, and lab manual from the sponsor as soon as possible once a decision has been made to participate (prior to submitting).
  - Amendments: Provide the contract amendment and/or revised budget as soon as possible and prior to submitting amendments that may impact funding, contracts or budgets. This may include PI changes, sponsor changes, funding changes, and/or any changes to the protocol that would impact the budget (increasing accrual; adding new procedures, visits or timepoints).
- ☐ Verify DF/HCC Training Requirements for the PI
  - New Protocols: Ensure the PI has completed the required new investigator training (one-time requirement), has up to date HSP and GCP training, and these trainings are reflected in their OnCore profile.
  - Amendments: Verify the above training requirements for any add site or PI change amendments.
- ☐ Verify the Reimbursement Plan
  - If subjects will be offered reimbursement, ensure that the reimbursement plan includes applicable language that covers all participating DF/HCC sites. Communicate with DF/HCC subsites as the reimbursement process may be different at each site.

Post-Activation:

Complete these tasks as soon as the submission activates.

- ☐ Communicate with DF/HCC Subsites
  - Immediately notify the core site study team and all participating DF/HCC sites when a submission activates.
  - Amendments: Indicate whether re-consent is required.

- ☐ Verify OncPro Documents / Add to Regulatory File
  - Verify that all the documents were posted to OncPro as expected.
  - **Download a copy** of the approved protocol, consent form and any other documents needed for the regulatory file.

- ☐ **For Phase I and I/II protocols only:** Confirm active dose level(s) and submit a separate dose/cohort form.
  - Consent and screening can begin if the study is Open to Accrual, but subjects cannot be enrolled or treated until at least one dose level is active.

- ☐ Confirm all DF/HCC Outside Interest Forms are complete
  - New Protocols: Ensure that a completed Outside Interest Form is on file for all Principal Investigators, sub-investigators, and any additional study personnel who are responsible for the design, conduct, or reporting of the research and will make a direct and significant contribution to the research.

  - Amendments: Ensure that any new research staff have completed an Outside Interest Form as required.

- ☐ Update study staff in OnCore and IRIS
  - New Protocols: Ensure that all applicable research staff are added to OnCore and IRIS.

  - Amendments: Ensure that any new research staff have been updated in iRIS and OnCore. **Do NOT make changes to any PI in OnCore.** Only OHRS is allowed to update PI information in OnCore after such changes are approved via an amendment in iRIS.

- ☐ Verify the OnCore Management Groups
  - New Protocols: Ensure that the appropriate management groups are listed in OnCore for study teams who will need access to the OnCore record. Email OHRS@dfci.harvard.edu if any changes need to be made.

  - Amendments: Ensure that the appropriate management groups are added whenever a research team or DF/HCC site is added to the study. Email OHRS@dfci.harvard.edu if any changes need to be made.

- ☐ Review contract/grant terms and data submission timelines
  - New Protocols: Ensure research team is aware of any unique or non-standard requirements.