Request to Add Site:
Required Documentation Checklist

Instructions: Please use the checklist as a guide to the requirements to add sites engaged in Dana-Farber/Harvard Cancer Center (DF/HCC) human subject research to DF/HCC led research studies.

DF/HCC Site(s)

- **Beth Israel Deaconess Medical Center, Boston Children's Hospital, Brigham and Women's Hospital, Dana-Farber Cancer Institute, Massachusetts General Hospital**
  - ☐ Request to Add Site / Remove Site Form
  - ☐ Signed *Statement of Principal Investigator -or- Statement of Site Responsible Investigator Form* for the new Site Responsible Principal Investigator (Note: this is not required if the new Site Investigator is already on the study as the Principal Investigator or Site Principal Investigator **and** the previously signed statement of investigator form is not changed by the site addition).
  - ☐ Revised Consent Form. The following changes are required:
    - Consent Form Header: Add the new Site Responsible Investigator name and site name
    - "What are the Costs?" Section: Add the new Site name and required contact information
    - "Whom do I contact if I have questions about the Research Study?" Section: Add the new Site Responsible Investigator name and required contact information including 24-hour contact
  - ☐ Revised Protocol, if applicable, identifying the new site. This is not required.
  - ☐ Research Administration Correspondence. If adding BIDMC to the study, please ensure that Clinical Research Agreements Office at DFCI (Email: Mary_Melloni@dfci.harvard.edu) has been notified prior to submission. Please include this correspondence.
  - ☐ Revised Radiation Safety Screening Form if there will be any use of ionizing radiation at the new site(s).

DF/HCC Satellite Site(s)

- **Beth Israel Deaconess Medical Center Needham, Beth Israel Deaconess Medical Center Plymouth**
- **Brigham and Women's Hospital at Faulkner Hospital**
- **Dana-Farber/New Hampshire Oncology-Hematology, Dana-Farber at Steward St. Elizabeth's Medical Center, Dana-Farber/Brigham and Women's Cancer Center (DF/BWCC) at Milford Regional Medical Center, Dana-Farber/Brigham and Women's Cancer Center (DF/BWCC) in clinical affiliation with South Shore Hospital**
- **Mass General / North Shore Cancer Center, Mass General Cancer Center at Emerson Hospital – Bethke, Mass General at Newton Wellesley Hospital**
  - ☐ Request to Add Site / Remove Site Form
  - ☐ Clinical Trials Request Form for DFCI Satellites only. The Clinical Trials Request Form is not required for retrospective medical record review research.

☐ Signed *Statement of Principal Investigator -or- Statement of Site Responsible Investigator Form* for the new Site Responsible Principal Investigator (Note: this is not required if the new Site Investigator is already on the study as the Principal Investigator or Site Principal Investigator **and** the previously signed statement of investigator form is not changed by the site addition).

☐ Revised Consent Form. The following changes are required:

- Consent Form Header: Add the new Site Responsible Investigator name and site name
- "What are the Costs?" Section: Add the new Site name and required contact information
- "Whom do I contact if I have questions about the Research Study?" Section: Add the new Site Responsible Investigator name and required contact information including 24-hour contact

☐ Revised Protocol, if applicable, identifying the new site. This is not required.

DF/PCC Network Affiliate Site(s) Under DFCI IRB

- **Cape Cod Healthcare, Lowell General Hospital, New Hampshire Oncology-Hematology-P.A., New England Cancer Specialists**

☐ Request to Add Site / Remove Site Form

☐ Clinical Trials Request Form. The Clinical Trials Request Form is not required for retrospective medical record review research.

☐ Signed *Statement of Principal Investigator -or- Statement of Site Responsible Investigator Form* for the new Site Responsible Principal Investigator (Note: this is not required if the new Site Investigator is already on the study as the Principal Investigator or Site Principal Investigator **and** the previously signed statement of investigator form is not changed by the site addition).

☐ Revised Consent Form. The following changes are required:

- Consent Form Header: Add the new Site Responsible Investigator name and site name
- "What are the Costs?" Section: Add the new Site name and required contact information
- "Whom do I contact if I have questions about the Research Study?" Section: Add the new Site Responsible Investigator name and required contact information including 24-hour contact

☐ Revised Protocol, if applicable, identifying the new site. This is not required.

☐ Revised Radiation Safety Screening Form if there will be any use of ionizing radiation at the new site(s).

DF/PCC Network Affiliate Site(s) Under External IRB

☐ Request to Add Site / Remove Site Form

☐ Clinical Trials Request Form. The Clinical Trials Request Form is not required for retrospective medical record review research.

☐ IRB Approval from the site's IRB of Record

☐ Revised Protocol, if applicable, identifying the new site. This is not required.

Multicenter Site(s) with Master Clinical Trials Agreements Under External IRB

- **Berkshire Medical Center, Eastern Maine Medical Center, Lifespan, Stamford Hospital.** Note: Dana-Farber Cancer Institute must be a participating site to add any of these Multicenter Sites.
  - ☐ Request to Add Site / Remove Site Form.
  - ☐ Clinical Trials Request Form. The Clinical Trials Request Form is not required for retrospective medical record review research.
  - ☐ IRB Approval from the site's IRB of Record
  - ☐ Revised Protocol, if applicable, identifying the new site. This is not required.

Harvard Catalyst Member Site(s) Under DFCI IRB (e.g. HMS, HSPH, Broad, etc.)

- ☐ Request to Add Site / Remove Site Form
- ☐ Harvard Catalyst Cede IRB Site Detail Form
- ☐ Signed *Statement of Principal Investigator -or- Statement of Site Responsible Investigator Form* for the new Site Responsible Principal Investigator (Note: this is not required if the new Site Investigator is already on the study as the Principal Investigator or Site Principal Investigator **and** the previously signed statement of investigator form is not changed by the site addition).
- ☐ Revised Consent Form. The following changes are required if the DFCI IRB approved Consent form will be used by the relying Harvard Catalyst site (unless consent or documentation of consent is waived):
  - *Consent Form Header:* Add the new Site Responsible Investigator name and site name
  - *"Whom do I contact if I have questions about the Research Study*?": Add the new Site Responsible Investigator name and required contact information including 24-hour contact
  - *Section O. Privacy of Protected Health Information, 4. Who will my information be shared with?:* When applicable, add the relying institutions full legal name.
- ☐ Revised Protocol if applicable, identifying the Harvard Catalyst Member site and what research activities will take place at the relying site. This is not required.
- ☐ Research Funding Form if funding information is included with this Add Site request.
- ☐ External Site Communications (if applicable):
  - Broad Institute Research Administration Correspondence is required from ORSP@broadinstitute.org.

Sample and/or Data Analysis by an External Site under the DFCI IRB: (e.g. Broad or MIT)

- ☐ Request to Add Site / Remove Site Form
- ☐ Co-Investigator Form for the External Site Collaborator responsible for the Data Analysis. ***Note:*** *The Overall PI for the study will be listed as the Site PI in OnCore for the added site. A new statement of investigator form is only required if any conflict of interest disclosures need to be made as a result of the site addition.*
- ☐ Revised Consent Form. The following changes are required:
  - *Section O. Privacy of Protected Health Information, 4. Who will my information be shared with?* Add the External Site name (e.g. "Broad Institute")
- ☐ Revised Protocol identifying what sample and/or data analysis will take place at the External Site.
- ☐ Site Detail Form. Please submit one form for each site being added.
- ☐ Multi-Center Coordinating Committee Approval Form
- ☐ Research Funding Form if funding information is included with this Add Site request.
- ☐ External Site Communications (if applicable):

- Broad Institute Research Administration Correspondence is required from ORSP@broadinstitute.org.

DF/HCC Led Multicenter Site(s) – United States under DFCI IRB:
REQUIRED: Please contact OHRS for more information about outside sites relying on the DFCI IRB before submitting a request to add an external site under the DFCI IRB.
http://www.dfhcc.harvard.edu/research/clinical-research-support/office-for-human-research-studies/research-with-biological-materials-data/

- ☐ Request to Add Site / Remove Site Form
- ☐ Site Detail Form Please submit one form for each site being added.
- ☐ Multi-Center Coordinating Committee Approval Form
- ☐ Local Context Form
- ☐ Revised Protocol, if applicable, identifying the new site. This is not required.

Multicenter Site(s) – United States and International Sites under External IRB:

- ☐ Request to Add Site / Remove Site Form
- ☐ Site Detail Form. Please submit one form for each site being added.
- ☐ Multi-Center Coordinating Committee Approval Form
- ☐ IRB Approval from the site's IRB of Record
- ☐ Revised Protocol, if applicable, identifying the new site. This is not required.

Resources and Links:

- OHRS Information Sheet - DFHCC Specimens and Data - External Sites Checklist
- OHRS Information Sheet – Institutional Engagement: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/IS_-_Guidance_-_Institutional_Engagement.pdf
- OHRS Engagement Determination Worksheet for Study Teams: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/HRP-311_-_WORKSHEET_-_Engagement_Determination.docx
- OHRS Information Sheet - Research Procedures at External Sites: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/IS_-_Guidance_-_Research_Procedures_at_External_Sites.pdf
- DF/HCC Standard Operating Procedures: http://www.dfhcc.harvard.edu/research/clinical-research-support/document-library-forms-sops-etc/dfhcc-sop-library/