Research Acquired Specimens and/or Data Analysis by an External Site

CHECKLIST

Instructions: Please use this checklist to ensure that minimum requirements are met when an External Site (e.g. Broad Institute, MIT, etc.) receives and conducts analysis on Dana-Farber/Harvard Cancer Center (DF/HCC) research acquired research samples and/or data.

For clinically acquired samples, please reference the OHRP Guidance on Coded Private Information or Specimens Use in Research, Guidance (2008): https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html

Determining Engagement in Human Subjects Research

Within the DF/HCC consortium the Overall Study team on a DF/HCC led study will be from one of the five clinical institutions that make up the DF/HCC:

- Beth Israel Deaconess Medical Center (BIDMC)
- Boston Children's Hospital (BCH)
- Brigham and Women's Hospital (BWH)
- Dana-Farber Cancer Institute (DFCI)
- Massachusetts General Hospital (MGH)

The Overall DF/HCC Study Team must first determine whether the research acquired data and/or specimens sent to an External Site for analysis constitutes human subjects research. To do this, the Overall DF/HCC Study Team must understand 1) what External Site(s) are involved in the research, 2) what will be shared with the External Site(s) and 3) what will be done with the information.

Please reference the OHRS Information Sheets on institutional engagement linked below to determine whether the External Site is engaged in the human subjects research or not. *Note: For the purposes of the Broad and MIT engagement determinations, the overall study team can work with OHRS Senior Staff or Polly Goodman (Senior HRC) on these questions.*

Resources and Links:

- 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

ENGAGED CHECKLIST

Step 1: IRB Review - Complete: ☐

If it is determined that the External Site is engaged in the research, follow the OHRS Add Site Checklist to add the External Site to the DF/HCC led research. The add site amendment must be approved by the DFCI IRB before research activities commence at the External Site.

Note: If an external sIRB is utilized, the Overall Study team will need to follow the processes of adding the External Site as set forth by the external sIRB.

Resources and Links:

- OHRS Information Sheet – Request to Add Site Checklist: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/IS_-_Operations_-_Request_to_Add_Site_Checklist.pdf
- DF/HCC Policies and Operation Library: http://www.dfhcc.harvard.edu/research/clinical-research-support/document-library/

Step 2: Agreements - Complete: ☐

An agreement to transfer samples/data to the External Site is always required. This is managed by the respective offices listed below at the lead (and participating institutions) where the samples/data are being transferred to/from. The institution providing the samples/data should be the lead on a Material Transfer Agreement (MTA) or Data Use Agreement (DUA).

A. For all Industry Studies with Clinical Trials Contracts (regardless of lead site) – the contact is Mary Melloni from the Dana-Farber Cancer Institute (DFCI).
   Contacts for CTAs at other sites:
   - Boston Children's Hospital (BCH): Fernando Valles
   - Beth Israel Deaconess Medical Center (BIDMC): Denise Graham

B. For all other studies:

Dana-Farber Cancer Institute (DFCI):
- **The Belfer Office for Dana-Farber Innovations (BODFI)** – BODFI staff handle MTA's/DUA's. Contact: Anita Ballesteros
- http://www.dana-farber.org/research/innovations/our-team/

Partners Healthcare (MGH and BWH):
- **Materials Transfer Agreements (Transferring Material To Research Collaborators) for general information, see** Data/Tissue Transfer Grid**.**
  - Transfer of samples/data to academic or non-profit entities or collaborators, refer to Investigator Checklist for Transfer of Tissue/Data to Academic Institutions.

  - Template Agreements for Coded Samples and Non-Identifiable Samples are available for transfers between academic or non-profit entities or collaborators
  - Transfer of samples/data to for-profit or commercial entities or collaborators, contact Partners Innovation.
- **Partners Innovation**: https://innovation.partners.org/
  - FAQ: https://innovation.partners.org/faqs
  - Cancer & Pathology Team: https://innovation.partners.org/our-team?wpv-staff-tags=cancerpathology

Boston Children's Hospital (BCH):

- **Boston Children's Hospital Technology and Innovation Development Office**
- http://tido.childrenshospital.org/

Beth Israel Deaconess Medical Center (BIDMC)

- **Technology Ventures Office at BIDMC**
- http://tvo.bidmc.org/for-bidmc/material-transfer-agreements/

Note: If the consent form does not permit the sharing/use, the agreement will not be initiated and samples cannot be sent to the External Site or outside collaborator.

Step 3: Human Subject Research Activities Begin - Complete: ☐

As permitted in the IRB approved research and the Material Transfer Agreement/ Data Use Agreement, External Site research analysis may begin once the materials are received.

The Overall Study Team for the research will have regular contact with the External Site to ensure that applicable DF/HCC policies and procedures for the conduct of research are followed.

DF/HCC Minimum Policy and Operations Documents Requirements for External Sites include:

- **MULTI-100**: Conducting PI-Initiated Multi-Center Trials
- Research Conduct Policies and Operations Documents as directed by the Overall Study Team
- Multi-Center Regulatory Binder Requirements will depend on the research conducted at the External Site. For more information about what is required, please contact the Lead Site's Clinical Trials Office:
  - BIDMC Cancer Clinical Trials Office (CCTO)
  - DFCI Clinical Trials Office (CTO)
  - MGH Cancer Center Protocol Office (CCPO)
- Research Close Out Policies and Operations Documents as directed by the Overall Study Team

NOT ENGAGED CHECKLIST:

Step 1: IRB Review - Complete: ☐

If it is determined that the External Site is NOT engaged in the research, **there is typically no submission required to the DFCI IRB (OHRS)**. There is no IRB engagement determination to be made.

Note: If an external sIRB is utilized, the Overall Study team will need to follow the processes for determining engagement in human subjects research as determined as set forth by the external sIRB.

Step 2: Agreements - Complete: ☐

An agreement to transfer samples/data to the External Site is always required. This is managed by the respective offices listed below at the lead (and participating institutions) where the samples/data are being transferred to/from. The institution providing the samples/data should be the lead on a Material Transfer Agreement (MTA) or Data Use Agreement (DUA).

C. For all Industry Studies with Clinical Trials Contracts (regardless of lead site) – the contact is Mary Melloni from the Dana-Farber Cancer Institute (DFCI).

D. For all other studies:

Dana-Farber Cancer Institute (DFCI):

- **The Belfer Office for Dana-Farber Innovations (BODFI)** – BODFI staff handle MTA's/DUA's. Contact: Anita Ballesteros
- http://www.dana-farber.org/research/innovations/our-team/

Partners Healthcare (MGH and BWH):

- **Materials Transfer Agreements (Transferring Material To Research Collaborators) for general information, see** Data/Tissue Transfer Grid**.**
  - Transfer of samples/data to academic or non-profit entities or collaborators, refer to Investigator Checklist for Transfer of Tissue/Data to Academic Institutions.
  - Template Agreements for Coded Samples and Non-Identifiable Samples are available for transfers between academic or non-profit entities or collaborators
  - Transfer of samples/data to for-profit or commercial entities or collaborators, contact Partners Innovation.
- **Partners Innovation**
- https://innovation.partners.org/
  - FAQ: https://innovation.partners.org/faqs
  - Cancer & Pathology Team: https://innovation.partners.org/our-team?wpv-staff-tags=cancerpathology

Boston Children's Hospital (BCH):

- **Boston Children's Hospital Technology and Innovation Development Office**
- http://www.childrensinnovations.org/Pages/PatentsAndLicensing/MTAsCDAsAndConsulting.aspx

Beth Israel Deaconess Medical Center (BIDMC)

- **Technology Ventures Office at BIDMC**
- http://tvo.bidmc.org/for-bidmc/material-transfer-agreements/

Note: If the consent form(s) does not permit the sharing/use, the agreement will not be initiated and samples will not be sent to the External Site.

Step 3: Research Related Activities Begin - Complete: ☐

As permitted in the Protocol and/or Material Transfer Agreement/ Data Use Agreement External Site data/specimen analysis activities may begin once the materials are received.