

### Guidance on Requesting OHRS Verification for the Transfer of Data or Specimens

For Principal Investigators that wish to transfer data or samples out of the institution, please contact your home institution's technology transfer department (e.g., BODFI, Innovations) to determine if a material transfer agreement (MTA) or data use agreement (DUA) is required. **Please Note:** IRB approval may still be required.

If your technology transfer office requests OHRS Verification for the transfer of data or samples, OHRS may need to review the governing protocol(s) and informed consent forms (ICF) to confirm that the proposed research and transfer are described in the study documents. OHRS will only provide an OHRS Verification for protocols for which the DFCI IRB is the IRB of record.

Questions about the OHRS Verification Process can be emailed to: [OPS\\_OHRS@dfci.harvard.edu](mailto:OPS_OHRS@dfci.harvard.edu)

Prior to requesting a MTA/DUA, review the relevant Protocol(s) and ICF(s) for the studies from which the collected data and/or specimens will be transferred. The Protocol(s) **and** signed ICFs must allow for the use of the data and/or specimens as proposed. The ICFs that the Participant(s) signed must include language that permits future research and sharing of data and/or specimens. Please ensure that the correct version(s) of ICF and the time frame of the collected samples are available. *For example*, if you wish to transfer samples collected between 6/21/2010 and 7/02/2012, then you must confirm that the ICFs signed by the Participant(s) between 6/21/2010 and 7/02/2012 includes the required language.

If the ICFs DO NOT ALLOW for the intended use or transfer of the data, follow these steps:

- If the ICFs do not provide for the proposed transfer of data, submit an amendment in iRIS to revise the ICFs to allow for the intended future use.
- If the proposed research is not covered by an existing protocol, submit a Secondary Use Protocol, or Not Human Subjects Determination in iRIS.

If the ICFs allow for the sharing of data, contact your technology transfer office to confirm what is required to draft the relevant MTA or DUA. If the study is covered by a clinical trial contract, contact the Clinical Trials Agreements Office.

If your tech transfer office requests confirmation from OHRS that the future use and sharing are permissible, email [OPS\\_OHRS@dfci.harvard.edu](mailto:OPS_OHRS@dfci.harvard.edu). In this email:

- Provide the protocol number which describes the research. This may or may not be the protocol under which the samples were collected.
- Identify the version(s) of the ICF that the participant signed when providing the samples.

OHRS will conduct an initial review of the request within 5 days of submission (the final review of the request can take between 5 and 20 days). If the OHRS reviewer has any questions, an OHRS staff

# Info Sheet – Verification Requests

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member will communicate these questions and/or requests for clarifications directly via email to the submitting investigator. Please respond and make necessary changes as requested.

Once the OHRS review has been completed, OHRS will provide a review email. The OHRS review will be limited to the requested verification.

## **Who to Contact:**

### **Dana-Farber Cancer Institute (DFCI):**

- Belfer Office for Dana-Farber Innovations (BODFI), **or** a member of your Cluster in BODFI <https://www.dana-farber.org/research/innovations/>
- For DF/HCC Clinical Trials contact: Mary Melloni, [Mary\\_Melloni@DFCI.HARVARD.EDU](mailto:Mary_Melloni@DFCI.HARVARD.EDU), Clinical Research Agreements Office (CRAO), **or** the Clinical Trial Agreement Associate for the trial
- Office of Human Research Protections (OHRS) atOPS [OHRS@dfci.harvard.edu](mailto:OHRS@dfci.harvard.edu)

**Partners (MGH and BWH):** Partners Innovation, <https://innovation.partners.org/>

**Beth Israel Deaconess Medical Center (BIDMC):** Technology Ventures Office, [tvo@bidmc.harvard.edu](mailto:tvo@bidmc.harvard.edu)

**Boston Children’s Hospital (BCH):** Technology and Innovation Development Department, <http://tido.childrenshospital.org/>