Guidance on the Transfer of Data or Specimens

IRB approval or exemption of research is needed for the use and transfer of data and specimens. If your institution's technology office (e.g., BODFI, Innovations) requires verification of appropriate IRB approval and consent language to create a material transfer agreement (MTA) or data use agreement (DUA), please contact OPS_OHRS@dfci.harvard.edu. OHRS will determine whether the IRB approval and consent documents allow for the transfer of the data.

For DFCI researchers, if a MTA or DUA is required, submit the Outbound Patients Materials Questionnaire to BODFI. The questionnaire will prompt the research team to provide the IRB number under which the samples are being shared, an explanation of when and how the samples were originally collected, the consent versions, and whether any collaborators were included in the collection of the samples. OHRS does not need to provide verification for studies that were determined to not be human subjects research or are secondary use studies without collaborators.

For biobanked studies, PDX models, cell lines, and other materials, OHRS may need to 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, commercialization, and sharing of data and/or specimens.

For non-DFCI researchers, or research overseen by another institution, please contact the appropriate technology office (e.g., Innovations) to determine what, if any, information is needed to create the MTA or DUA.

If BODFI requests further information from OHRS that the future use and sharing are permissible, the tech transfer office will contact OHRS directly for confirmation. If the OHRS reviewer has any questions during their review, an OHRS staff member may 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 review has been completed, OHRS will provide an email to the appropriate tech transfer office.

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, Clinical Research Agreements Office (CRAO), **or** the Clinical Trial Agreement Associate for the trial

- Office of Human Research Protections (OHRS) at OPS_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

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