Guidance on Data Sharing Statements for Investigator-Sponsored Research

In an editorial published at Annals.org on June 6, 2017, ICMJE announced new requirements for data sharing statements intended to encourage responsible and ethical sharing of data from clinical trials. Beginning July 1, 2018, manuscripts submitted to ICMJE journals must contain a data sharing statement. In addition, for trials that begin enrolling participants after January 1, 2019, the data sharing statement must be part of the trials registration (e.g., on Clinicaltrials.gov). This document provides guidance to DF/HCC investigators on how to fulfill these requirements.

Background
The sharing of research data is subject to the terms and conditions of any written agreement or award which funds the research, including in-kind support, as applicable. Regardless of the funding source, data cannot be shared outside of the DF/HCC unless permission is obtained from supporters of the research, and/or such sharing is allowable under the agreement or award which funds the research. The sharing of research data is furthermore subject to the institutional policies of the participating investigator's home institution. In the event institutional policy conflicts with DF/HCC policy, the stricter of the two will apply.

Secondary Use
Data generated as a result of secondary research on banked samples or previously collected research data are subject to any existing restrictions in place (contractual or otherwise) for the primary research under which the samples/data were collected.

Industry-Supported Research
Data originating from industry-supported research cannot be shared unless or until the DF/HCC Sponsor-Investigator consults with and receives written permission (via an email or contract amendment) from all industry parties supporting the research or the DF/HCC Sponsor-Investigator confirms the provisions of the existing Clinical Trial Agreements contain no restrictions and allow such sharing. The DF/HCC Sponsor-investigator should first consult with his/her home institution's Clinical Trials Contracts Office to review the terms of the Agreement. When sharing or posting research documents to Clinicaltrials.gov (e.g., protocol, statistical analysis plan, informed consent document), the industry parties supporting the research must be given ample opportunity to redact confidential information from the documents prior to posting.

All Research
The Sponsor-Investigator must verify with their home institution's technology innovations office that there are no licensing or intellectual property concerns that would limit or prevent the sharing of research data.

- BCH – Contact the Technology & Innovation Development Office at www.childrensinnovations.org or email TIDO@childrens.harvard.edu
- BIDMC – Contact the Beth Israel Deaconess Medical Center Technology Ventures Office at tvo@bidmc.harvard.edu
- BWH – Contact the Partners Innovations team at http://www.partners.org/innovation
- DFCI – Contact the Belfer Office for Dana-Farber Innovations (BODFI) at innovation@dfci.harvard.edu
- MGH – Contact the Partners Innovations team at http://www.partners.org/innovation

When data sharing is permitted (DF/HCC policy, institutional policy, terms and conditions of agreements and awards), a data sharing Data Use Agreement (DUA) specifying the uses of such data to be shared must be put in place before any data is shared. The Sponsor-Investigator should contact their institutional Clinical Trials Contracts Office for assistance with the DUA.

- Only de-identified participant data from the final research dataset used in the published manuscript can be shared.
- Data shall only be shared upon request with researchers who provide a methodologically sound research proposal, at the discretion of the principal investigator.
- Data can be shared no earlier than 1 year following the date of publication.

The protocol and statistical analysis plan will be made available on Clinicaltrials.gov only as required by federal regulation or when such posting is a condition of funding/support for the research

Data Sharing Statements
Here is the template data sharing statement that may be included in submissions to ICMJE or in a trial's Clinicaltrials.gov record:

The Dana-Farber / Harvard Cancer Center encourages and supports the responsible and ethical sharing of data from clinical trials. De-identified participant data from the final research dataset used in the published manuscript may only be shared under the terms of a Data Use Agreement. Requests may be directed to: [contact information for Sponsor-Investigator or designee]. The protocol and statistical analysis plan will be made available on Clinicaltrials.gov only as required by federal regulation or as a condition of awards and agreements supporting the research.