Research and Technology Management

MSK's Policy on NIH Data Sharing

April 2020

As a recipient of NIH grant funds, Memorial Sloan Kettering Cancer Center (MSK) is required to comply with all applicable provisions set forth in the <u>NIH Grants Policy Statement</u> (Revised December 2019), including <u>§8.2.3.1 Data Sharing Policy</u> for NIH grants and cooperative agreements for budget periods beginning on or after October 1, 2019.

Per NIH Grants Policy:

Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data* to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. All investigator-initiated applications with direct costs of \$500,000 or more (excluding consortium F&A costs) in any single year are expected to address data-sharing in their application. In some cases, FOAs may request data-sharing plans for applications that are less than \$500,000 (excluding consortium F&A costs) in any single year.

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the HIPAA Privacy Rule (see <u>Public Policy Requirements and Objectives-Confidentiality of Patient Records: Health Insurance Portability and Accountability</u>). The rights and privacy of individuals who participate in NIH-sponsored research must always be protected. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to meet these expectations should promptly contact the GMO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

Meeting MSK's Intellectual Property and Third-Party Obligations: This includes complying with MSK's obligation under Bayh-Dole to report to federal funding agencies on inventions resulting from federal funds, as well as with third-party obligations resulting from extramural sponsored research agreements

or material transfer agreements. In devising a data sharing plan, investigators must consider the need to allow adequate time for review by the MSK's Office of Technology Development (OTD) of intellectual property and/or proprietary information that must be protected prior to release of research data. The NIH Implementation Guidance recognizes the need to protect patentable and other proprietary data (including cases where co-funding is provided by the private sector) and notes reasonable delays in disclosure of research findings may be needed to accomplish this goal.

Links to other NIH Data Sharing resources can be found at the following website: http://grants2.nih.gov/grants/policy/data sharing/

For questions regarding this policy, please contact the Office of Research and Projects Administration at sponsorp@mskcc.org.

*For definition of "research data," and more information on data retention and access, see <u>RTM-1002</u>. For information on policy and procedures on data use and transfer, see <u>RTM-1020</u>.