Data Sharing Policy

August 2015

As a recipient of NIH grant funds, Memorial Sloan Kettering Cancer Center is required to comply with all applicable provisions of the Final NIH Statement on Sharing Research Data, as set forth in NIH Notice NOT-OD-03-032 at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html and in the March 5, 2003 NIH Data Sharing Policy and Implementation Guidance at: http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

Per this Notice, as of October 1, 2003:

(a) All investigator-initiated grant applications to the NIH with direct costs in excess of $500,000 in any single year should include a data sharing plan in the grant application or state why data sharing is not possible. This requirement applies to NIH-supported basic research, clinical studies, surveys, human subjects research, and non-human subjects research.

(b) The data sharing plan should address the sharing of "Final Research Data" for research purposes. The term "Final Research Data" is defined in the NIH Data Sharing Policy and Implementation Guidance cited above.

(c) For NIH Requests for Applications (RFA), Request for Proposals (RFP) and Program Announcements (PA), investigators should follow the instructions related to data sharing that are included in the RFA, RFP or PA. PAs may request data sharing plans for applications that are less than $500,000 in direct costs in a single year.

(d) Preparation of data sharing plans may be complex, and care should be taken to insure that institutional policies, local IRB rules, and local, state and federal laws and regulations are followed. In particular, investigators should carefully consider the following areas when developing data sharing plans:

- **Protecting the Rights and Privacy of Human Subjects:** This includes complying with all applicable IRB rules and the federal Health Portability and Accountability Act (HIPAA) pertaining to protected health information. In determining how best to make final research data available, investigators must consider the need to protect against disclosure of personally identifiable data (or de-identify data when appropriate).

- **Meeting MSK's Intellectual Property and Third-Party Obligations:** This includes complying with the 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.

(e) In addition to reviewing the NIH Data Sharing Policy and Implementation Guidance, Investigators should consult the following NIH resources in developing and implementing data sharing plans: (a) NIH Guide Notice dated 2/26/2003; (b) NIH Guide Notice dated 3/1/2002; (c) Frequently Asked Questions – Data Sharing; (d) Data Sharing Workbook; (e) NIH Data Sharing Brochure; (f) Testimonials; (g) Other Data Sharing Documents and Resources.

Links to all of these 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.