Policy and Procedures for Research Data Retention and Access

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Rationale and Purpose: Memorial Sloan Kettering Cancer Center (MSK) research investigators, faculty, staff, trainees, and students all share in the obligation to retain research data in appropriate form, archive it for a reasonable length of time, and make it available for collaborative research and for review under the appropriate circumstances.

Contact Person: Senior Vice President, Research and Technology Management

Definitions: It is important for institutions and the members of the research community to be knowledgeable about the definition of the terms "research" and "research data" in the context of specific federal regulations and institutional policy.

Research: Research is defined as "a systematic investigation designed to develop and contribute to generizable knowledge." Examples of activities that constitute research include any biomedical or biobehavioral study intended to result in publication or public presentation; any activity resulting in publication or public presentation, even though it involves only review of existing data that were collected with no intent to publish; or any use of an investigational drug or device.

Research Data - Federal Definitions: The National Institutes of Health (NIH) Grants Policy Statement defines research data as "recorded information, regardless of the form or medium on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data."

In the Office of Management and Budget's (OMB) Uniform Guidance ("*Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,"* December 26, 2013, A-81 section 200.315) the definition of "research data" is almost identical to the previous OMB A-110 definition.

> *Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g.,*

laboratory samples).
Research data also do not include:
(i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
(ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

Research Data - MSK Definition: For the purposes of this policy, "research data" are defined as the material, originally recorded by or for the Investigator, commonly accepted in the scientific community as necessary to validate research findings. Research data include, but are not limited to, laboratory notebooks and electronic files, as well as any other records that are necessary for the reconstruction and evaluation of reported results of research and events and processes leading to those results, regardless of the form or the media on which they are recorded. In clinical investigations, this can include case history records and the study protocol.

Principal Investigator: The Principal Investigator (PI) is defined as the person responsible for the research or who is the signatory person for the research.

Data Retention: MSK must retain research data in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy, and compliance with laws and regulations governing the responsible conduct of research.

The PI is the custodian of the research data, unless otherwise agreed in writing or dictated by institutional policy, and is therefore responsible for the collection, management, and retention of the research data. An orderly system of data organization should be adopted and clearly communicated to all members of the research group and to the appropriate administrative personnel, where applicable. Particularly for long-term projects, the PI should establish and maintain procedures for the protection of essential records.

Retention Guidelines:

1. Research data must be retained in the research unit or within the institution.
2. Upon leaving MSK employment, the PI must inform the appropriate parties (e.g., lab head, service chief, department chairperson, institutional officials) of the nature and location of all research data currently retained in his or her custody.
3. MSK research data must be archived for a minimum of three years after the final close-out or publication, whichever occurs last, with original data retained whenever possible. This should include reasonable and prudent practice for off-site back-up of electronic and hard-copy data. Appropriate measures to protect confidential information must be taken. In addition, any of the following circumstances may warrant longer periods of retention:
    a. Data pertaining to patient rights that involve Protected Health Information (PHI) or other pertinent information such as medical records, protocols, case history forms, clinical trial agreements, as well as progress reports and final reports must be retained for a minimum of seven years after the date of the last patient visit or for minor

patients, the latter of seven years from the last patient visit or age 21 – whichever is longer, or until such patient rights are determined to be of no further value; PIs who maintain research databases for which a waiver of patient authorization was granted have additional record maintenance responsibilities related to HIPAA. More information is available on the HIPAA intranet site;

b. Data must be kept for as long as necessary to protect any data that are required in support of a patent or other protected intellectual property resulting from the work;
c. If any charges/allegations of research misconduct (See RTM-1001) or conflict of interest arise from the research, data must be retained until such charges are fully resolved; and
d. If the data constitutes part of a student's work toward a degree, the data must be retained until the degree has been awarded or it is clear that the student has abandoned the work.

Access: To enable MSK to meet its responsibilities related to the custody of research (as previously described), the PI is obligated, upon appropriate request, to make all data available for review by institutional officials or bodies, external funding agencies, journals, or other external regulatory agencies. This obligation continues even after the PI leaves MSK.

Collaborations: In group/collaborative research projects, the PI is obligated to give co-investigators access to the research data or copies thereof for review and/or use in follow-on research, with proper acknowledgement. Data sharing (see RTM-1010) and custody arrangements should be determined by the investigators when joining the project and preferably defined in a data use agreement. In certain situations, data sharing plans that represent commitments made as part of a federally-supported research project will dictate access requirements.

Storage: Unless other arrangements are dictated by institutional policy, research data must be retained in the unit where they are produced and in such a manner that they are accessible for inspection and copying by authorized MSK representatives at reasonable times and in a reasonable manner. Where this is not physically possible, data must be available for retrieval in a similarly reasonable fashion.

Transfers: When individuals who are not PIs leave the institution, they may take copies of research data for projects on which they have worked. The PI must retain the original data at MSK.

If a PI leaves MSK, custody of the original data may be transferred as long as MSK is provided with a copy of the data and there is a *written agreement** signed by the Senior Vice President of Research and Technology Management or his/her designee and either the PI or (in the event the project is moved to another institution) both the PI and the new institution that guarantees acceptance of the custodial responsibilities for the original data, and provides assurance that MSK be given access should that become necessary.

**See RTM-1003 for Sample Written Agreement*