MOUNT SINAI NEW YORK POLICIES AND PROCEDURES	SUBJECT NO. H-45
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DEPARTMENT: All **SUBJECT: Ownership of Research Data**	

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Reviewed:	2/08	2/09	6/10				
Revised:							

Relevant Policies: Confidentiality of the Medical Record (A104.5); Uses and Disclosure for research (M.1.6.2.); Data Retention policy: Research Records (ACD:25-9)

Definitions:

Data –

1. "Recorded information, regardless of the form or medium on which it may be recorded, including 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."[1]

2. "Recorded factual material commonly accepted in the scientific community as necessary to validate research findings" **excluding** "preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues."[2]

Waiver of Authorization –

Permission granted by the Institutional Review Board (IRB) to a researcher on a case by case basis to access protected health information (PHI) without patient consent if

[1] The National Institutes of Health (NIH) Grants Policy Statement in "Access to and Retention of Research Data: Rights and responsibilities," Council on Governmental Relations, March 2006, p. 5.

[2] "Uniform Administrative Requirements for Grants and Agreements with Institution of Higher Education, Hospitals, and Other Non-Profit Organizations", (OMB) Circular A-110, Ibid.

1) the research could not be practicably carried out if subject consent were required; and
2) the research does not present more than minimal risk to the privacy of the subject; and
3) the research could not be carried out without access to identifiable subject data.[3]

Policy:

1. Regardless of the final disposition of the grant, the original research files and/or database(s) must remain at Mount Sinai School of Medicine (MSSM) despite the Principal Investigator's (PI's) departure. Where permitted under this policy, only a copy of the research file and/or database may be taken by the PI.
2. It is the responsibility of the Department to plan for secure retention of research files, records and data for the period of time required by the funding source or as required by the faculty handbook or IRB regulations whichever period is longer.
3. Any data that includes PHI may not be transferred outside MSSM until the IRB determines whether to issue a waiver of HIPAA authorization or to require that each study subject authorizes the disclosure to another institution.
4. Any disputes with respect to this policy shall be resolved by the Dean for Academic and Scientific Affairs for the School of Medicine and Senior Vice President for Health Sciences at the Medical Center.

Purpose:

1. To insure the integrity, confidentiality and availability of research data.
2. To delineate the rights and responsibilities of both the institution and the PI vis a vis the research data.

Procedure:

I. Research data and the databases in which it is stored belong to MSSM with various provisos, depending on the sponsor of the grant, if any, as follows:
   A. NIH sponsored grants are held by the institution on behalf of the PI.
      1. If the PI leaves the institution and the grant is transferred

[3] 45 CFR 164.512(i)

a. Copies of research files and databases that do not include PHI go with the PI to the new sponsoring institution.
b. Copies of clinical trial records and databases containing PHI may leave the institution only with either a HIPAA authorization from each study subject or an IRB approved waiver of HIPAA authorization.

2. If the PI leaves the institution and the grant has already ended or the nature of the grant requires termination when the PI leaves the institution:
    a. Copies of research files and databases that do not include PHI may go with the PI to the new sponsoring institution.
    b. Copies of clinical trial records and databases containing PHI may leave the institution only with either a HIPAA authorization from each study subject or an IRB approved waiver of HIPAA authorization.

3. If the PI leaves the institution and the grant is non-transferable as per the terms of the award, the PI chooses not to transfer the grant or MSSM determines that the PI is incapable of continuing the management of the grant after s/he leaves,
    a. MSSM will petition the NIH or other funding agency to keep the grant and assign a new PI.
    b. If the PI does not leave in good standing in relation to the grant s/he may not take any research file copies or databases.
    c. If the PI leaves in good standing in relation to the grant,
        1) copies of research files and databases that do not include PHI may go with the PI to the new sponsoring institution.
        2) copies of clinical trial records and databases containing PHI may leave the institution only with either a HIPAA authorization from each study subject or an IRB approved waiver of HIPAA authorization.

4. If a PI goes into private practice but remains on Mount Sinai's voluntary physician staff, while the grant continues with Mount Sinai as the sponsoring institution, all items necessary to carry out the grant activities and purchased with grant funds may go with him//her including copies of research files and/or databases.

B. Other external funding agencies will follow the NIH model unless specific regulations or sponsoring requirements preclude these procedures.

C. If the PI of an ongoing commercial grant leaves MSSM

1. The original research data (case report forms) go to the sponsor to the extent required by the terms of the grant and authorized by the research subjects.

2. The original research files (source documents) are maintained by MSSM.
3. Copies of case report forms and research files containing PHI may leave the institution only with either a HIPAA authorization from each study subject or an IRB approved waiver of HIPAA authorization.

D. If the PI of an unfunded grant sponsored by MSSM leaves the institution,

1. In the absence of a specific situation to the contrary, the data belong to MSSM.
2. Copies of clinical trial records and databases containing PHI may leave the institution only with either a HIPAA authorization from each study subject or an IRB approved waiver of HIPAA authorization.

II. The data generated during clinical research conducted under an IRB-approved waiver of HIPAA authorization shall be handled as follows:

A. In the absence of a specific situation to the contrary, the data belong to MSSM.

B. If the study is NIH funded, ownership of the data will be determined at the time of project consideration on a case by case basis.

Reference: Faculty Handbook, Chapter VII, B.
Handbook for Research, Section II
"Access to and Retention of Research Data: Rights and responsibilities," Council on Governmental Relations, March 2006.
"(OMB) Circular A-110: Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations," www.whitehouse.gove/omb/circulars/a110/a110.html
45 CFR164.512(i)