

APPLIES TO: ALL DDPSC Scientific Employees, Students, Visiting Scientists

TITLE: RETENTION OF AND ACCESS TO RESEARCH DATA

PURPOSE: Maintaining accurate and appropriate research records is an essential component of any research project, and is necessary to support and substantiate findings, protect intellectual property rights, facilitate management of the research programs within the Donald Danforth Plant Science Center (the "Danforth Center" or "Center") and to ensure compliance with federal regulations.

This policy sets forth the rights and responsibilities of the Center, the Principal Investigator (PI) and all other scientific employees with respect to access and maintenance of original Research Data created in connection with the design, conduct or reporting of research performed at or under the auspices of the various laboratories within the Center.

I. DEFINITION OF RESEARCH DATA

Research Data means any recorded, retrievable information necessary for the reconstruction and evaluation of reported results created in connection with the design, conduct or reporting of research performed or conducted at or under the auspices of the Center and the events and processes leading to those results, regardless of the form or the media on which they may be recorded. Research Data include, but are not limited to, both intangible data (statistics, findings, conclusions, etc.) and tangible data (laboratory notebooks and electronic files, printouts, etc.).

II. POLICY

It is important that investigators have the ability to document the results of research to assist the Center in meeting its scholarly and legal requirements as well as for establishing priority for patentable items, publishing manuscripts, etc. The Center must retain original Research Data in sufficient detail and for a required period of time to enable appropriate responses to questions about accuracy, authenticity, primacy and compliance with laws and regulations governing the conduct of the research and to establish priority for patentable items.

The Center claims ownership of any Research Data covered by this Policy and researchers shall make no assignments or commitments that might preclude such ownership.

III. RESPONSIBILITIES

A. The Danforth Center

The Danforth Center's responsibilities and rights over Research Data and stewardship of the scientific record for projects are based on both federal regulations and sound management principles.

The Center's responsibilities in this regard include, but are not limited, to:

- complying with federal grant requirements with respect to the retention of Research Data to support grant payments;
- complying with the terms of sponsored project agreements;
- protecting the rights of students, postdoctoral appointees, staff and other collaborators, including, but not limited to, their rights to access to data from research in which they participated;
- ensuring the appropriate use of recombinant DNA, biological agents or toxins, etiological agents, radioactive materials, and the like;
- securing the Center's intellectual property rights; and
- facilitating potential investigations such as allegations of research misconduct or conflict of interest.

B. The Principal Investigator

The Principal Investigator (PI) is the custodian for the Center of Research Data, including the scientific data and other records of research conducted at or under the auspices of the Center, holds original Research Data in trust for the Center, and is responsible for the maintenance and retention of Research Data in accordance with this policy.

The PI is responsible for:

- the identification, collection, management and retention of Research Data as custodian for the Center:
- ensuring that, for all aspects of a research program, sufficient records are kept to
 document the experimental methods and accuracy of data collection as well as the
 methods and accuracy of data interpretation;
- adopting an orderly and dated system of data organization;
- communicating this policy and the chosen system of data organization to all members of the research team, including appropriate administrative personnel;
- assuring access to the data in the event of a departure from the Center, under such terms as the Center approves by any member of the research team;
- facilitating the investigation of charges, such as research misconduct or conflict of interest:

- complying with funding agency requirements regarding data access and retention;
- establishing and maintaining procedures, particularly for long-term research projects, for the protection of essential records in the event of a natural disaster or other emergency, and securing such records in such event;
- assuring that in the event the data are associated with inventions or tangible research property that the Center wishes to commercialize through licensing or other means, the Center can assert ownership of the underlying data.

IV. RETENTION

All Research Data must be archived for the longer of (i) three years after the final project close-out or (ii) five years after the final reporting or publication of a project, with original data retained wherever possible. Sponsored research grants, contracts and cooperative agreements may mandate different retention periods, and investigators need to read and understand award terms and conditions to ascertain the requirements covering a particular sponsored research project.

In addition, certain research circumstances may justify longer periods of retention. Some common research circumstances where the Center may require a longer retention period are:

- if any intellectual property resulting from the work has been or is likely to be commercialized by the Center, Research Data must be kept for as long as may be necessary to protect it;
- if any charge, audit, claim or litigation regarding the research arises, such as allegations of scientific misconduct or conflict of interest, data must be retained for seven (7) years after the completion of the proceeding adjudicating such charge, audit, claim or litigation is fully resolved and final action is taken; and
- if a student is involved, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.

Beyond the period of retention specified here, or other applicable retention period, the destruction of the research records is at the discretion of the PI and should be documented by the PI.

In circumstances that do not permit the orderly execution of the provisions of this policy (e.g., death of the PI), the Vice President of Research shall assume responsibility of the Research Data or shall appoint a successor investigator to carry out the obligations.

V. ACCESS

The Center has the right of absolute access to Research Data arising from all research conducted at or under the auspices of the Center or supported by Center funds. The Center's right of absolute access to the Research Data shall continue regardless of the location of the responsible investigator.

Where necessary to assure needed and appropriate access, the Center has the option to take physical custody of the data in a manner specified by the Vice President of Research (or a designee).

Other Center investigators associated with a collaborative research project may have the need to review records of Research Data in the custody of the PI for the project. Research data must be available to such investigators, when such access is appropriate.

External sponsors providing support for research at the Center may also have the right to review the Research Data and records resulting form that support. Research Data must be available to representatives of external sponsors of the research or designated governmental officials, when such access is appropriate.

VI. TRANSFER IN THE EVENT A RESEARCHER LEAVES THE CENTER

When individuals other than the PI who are involved in research projects leave the Center, they may take copies of Research Data for projects on which they have worked unless restricted by the specific terms of the applicable agreement with the sponsor of the research. Original data, however, must be retained at the Center by the PI.

If a PI leaves the Center, and a project is to be moved to another institution, original Research Data may be transferred with the approval of the Vice President of Research (or a designee), and with written agreement from the PI's new institution that guarantees: 1) its acceptance of custodial responsibilities for the data, and 2) the Center's access to the data, should that become necessary.

The Center may refuse to permit the transfer of original Research Data for any reason, may impose conditions beyond those stipulated in this policy on such transfer, or may ask the PI to leave copies of the Research Data with the Center. In addition, other Center investigators associated with a collaborative research project may make copies of Research Data prior to a permitted transfer by the PI, unless restricted by the specific terms of the applicable agreement with the sponsor of the research.

When the Center permits the PI to leave the Center with original Research Data, he or she must retain the Research Data for the period required by this policy and recognize that the Center may need access to the Research Data. Departing PIs have an obligation to hold the Research Data in trust for the Center and must return the Research Data to the Center if requested during the retention period outlined in this policy. In addition, during the required retention period, such Research Data must be available to external sponsors, designated government officials, and other Center investigators associated with the collaborative research project, as appropriate.

Investigators should note that many contractual agreements require the sponsor's consent before Research Data are transferred or removed from the Center. Before transferring the original

Research Data, the PI is responsible for ensuring that any special conditions stated in the grant, contract or agreements are met.

Questions on the interpretation of this policy may be directed to the Vice President of Research.

ORIGINAL ISSUE DATE: June 1, 2012

EFFECTIVE DATE: June 1, 2012

EFFECTIVE DATE OF REVISION:

AUTHORIZED BY: Toni M. Kutchan

Vice President of Research

RESOURCES

<u>Policy on Retention of and Access to Research Data</u>, New York University, March 1, 2010. <u>http://www.nyu.edu/content/dam/nuy/research</u>

Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age http://www.nap.edu/catalog.php?record id=12615

Office of Management and Budget, Circular A-110 (Relocated to 2 CFR, Part 215) http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a110/2cfr215-0.pdf

National Institutes of Health (NIH) Office of Extramural Research http://grants1.nih.gov/grants/oer.htm

Statement on Sharing Data Policy (Notice # NOT-OD-03-032; Released February 26, 2003) http://grants1.nih.gov/grants/policy/data_sharing/index.htm

NIH Grants Policy, Part II Subpart A, Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources. http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part 7.htm#_Toc54600131

Public Health Service Policy Relating to Distributions of Unique Research Resources Produced with PHS.

http://grants.nih.gov/grants/guide/notice-files/not96-184.html

Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts.

http://www.nih.gov/science/models/sharing.html

Policy on Sharing Model Organisms for Biomedical Research (Notice #NOT-OD-04-042; Released May 2, 2004) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html

National Science Foundation (NSF) Grant Policy Manual (NSF 05-131) http://www.nsf.gov/pubs/manuals/gpm05_131/gpm7.jsp#734 &734. Dissemination and Sharing of Research Results

Federal Acquisition Regulations (FAR)
http://ecfr.gpoaccess.gov/
(For contracts awarded by the Federal government)
&27.403 Data rights—general
52.227-14 Rights in Data – General (Clauses & Forms)

Access to and Retention of Research Data, Council on Governmental Relations publication. Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age, the National Academies Press, July 2009 http://www.nap.edu.catalog/12615.html

SIGNATURE PAGE

By signing below, I acknowledge that I have read and understand the attached policy and will comply with its requirements.

Please sign and return this page to Human Resources, 975 North Warson Road, St. Louis, MO 63132.

	Date:	
Employee Signature		
Print Name		
	Date:	
Toni M. Kutchan		
Vice President of Research		

7