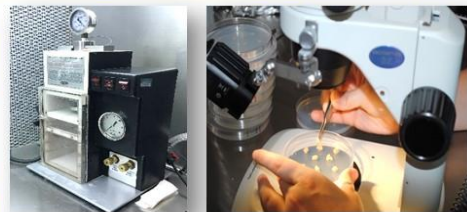


PLANT TISSUE CULTURE AND TRANSFORMATION FACILITY POLICIES AND GUIDELINES



DONALD DANFORTH
PLANT SCIENCE CENTER
DISCOVERY | COMMUNITY | IMPACT



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Introduction

The Donald Danforth Plant Science Center is a non-profit, academic research institute located in St. Louis, Missouri in the heartland for crop production in the United States. The Plant Tissue Culture and Transformation Facility (“*TC Facility*”) is an integral part of the Danforth Center's core research facilities.

LABORATORY SPACE AND EQUIPMENT

- The Facility consist of more than 2200 square feet of space.
- Facility contains equipment necessary for plant tissue culture and transformation.

CULTURE GROWTH SPACE

- 4 Conviron walk-in growth chambers
- 11 temperature controlled incubators

EQUIPMENT

- 16 laminar flow hoods with the capacity for 27 people at once
- Incubator shakers
- Spectrophotometer
- Centrifuge
- Dissecting microscopes
- Inverted microscope
- Fluorescence Microscope
- Electroporator
- BioRad PDS-1000 Gene delivery System

MEDIA PREPARATION AREA

- Autoclave & dishwasher
- Basic chemicals
- Glassware & consumables



Plant genetic engineering through the recent developments in targeted gene-editing has highlighted the importance of plant transformation in multiple areas from functional genomics to crop improvement. Over the years of its existence, the TC Facility has produced transgenic plants from tobacco, petunia, tomato, Arabidopsis, soybean, Indian mustard, maize, cassava, sweet potato, potato, and most recently green foxtail (*Setaria viridis*).

The TC Facility is enabling progress in plant research by development and optimization of transformation technologies in both model and crop plant systems, providing self-service training and access to state-of-the-art equipment and high quality space for researchers and companies use that are external to the Danforth Center.

The TC Facility also provides full-service research and consulting services to academic and commercial researchers external to Danforth Center, delivering transgenics and cell cultures utilizing our state-of-the-art equipment.

***These Policies and Guidelines are applicable to all on-site Users of the
Plant Tissue Culture and Transformation Facility***

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Related Policies and Forms located on the TC Facility Website and Referred to Herein:

1. TC Facility Self-Service Request Form
2. TC Facility Full-Service Request Form
3. Equipment Scheduling and Use Policies
4. External User Program
5. Lab Safety and Clean-up Policies
6. Visitor Tours Hosted by External or Danforth Users

Mission Of The Plant Tissue And Transformation Facility

To provide state-of-the-art plant transformation and genome modification services to accelerate crop improvement.

TC Facility Contact Information

<u>Department</u>	<u>Email</u>	<u>Phone</u>
TC Facility Staff:		
Veena Veena Facility Director	vveena@danforthcenter.org	(314) 587-1435
Dave Busby Laboratory Technician	dbusby@danforthcenter.org	(314) 587-1622
Preethi Vallal Laboratory Technician	pvallal@danforthcenter.org	(none)
<hr/>		
Danforth Safety Office:		
Jim Cox, Compliance Manager	jcox@danforthcenter.org	(314) 587-1056
<hr/>		
Danforth Security Office:		
Keith May, Security Manager	kmay@danforthcenter.org	(314) 587-1094
<hr/>		
Emergency/After Hours:		
Police/Fire/Medical (emergency)		911

A. Services Provided to Various Users of TC Facility

All officers, directors, full and part-time employees, Post-Doc students and interns of Donald Danforth Plant Science Center are considered “*Danforth Users*”.

There are six research areas of the Danforth Center that are accessible to External Users (defined below), which areas are called the “*Core Facilities*”. These Policies and Guidelines apply only to the Core Facility known as the Plant Tissue Culture & Transformation Facility (“*TC Facility*”). Those Danforth Users who work in the TC Facility are “*TC Facility Staff*”.

Although the primary mission and research activities of Danforth Center must take first priority, Danforth Center provides the following services and encourages the use of its Core Facilities by External Users, as defined below, to achieve mutually beneficial objectives.

1. SELF-SERVICE

a. External Academic Users

An External Academic User is anyone who is not a Danforth User, but who works for a university or other academic institution, either in collaboration with the Danforth Users or in performing an approved “self-service” research activity utilizing the Danforth Center Core Facilities under a separate Use License Agreement, which includes any persons who are employees, contractors, or consultants of any such External Academic User.

b. External Non-Academic Users

External Non-Academic Users include persons who are not affiliated with an academic institution (including for-profit or not-for-profit organizations) who are performing an approved “self-service” research activity utilizing the Danforth Center Core Facilities under a separate Use License Agreement, which includes any

persons who are employees, contractors, or consultants of any such External Non-Academic User.

c. Internal Danforth Users

“*Internal Danforth Users*” are Danforth Center Personal Investigators who request the TC Facility Staff to perform full-service activities or who request that Internal Danforth User staff be permitted self-service privileges in the TC Facility.

To initiate the process to become a self-service user of the TC Facility, please go to the TC Facility Web Page (address located under Section B(1)(a)) to select the “*Self-Service Request Form*.” Submit the completed form to the Director, who will contact you within 5 business days of receipt of the request form to discuss your needs, the contracting requirements and pricing options.

Access to the TC Facility by Self-Service External Users may be restricted or denied at the discretion of the Director or management of the Danforth Center for any reason. Reasons for denying access include, but are not limited to: the work to be performed is considered a) counter to the best interests of the Danforth Center and its mission, b) it jeopardizes the safety or security of other Users, c) it involves use or manufacture of materials classified for National Security reasons, or d) for any other reason that interferes with the activities within the TC Facility

2. FULL-SERVICE

Full-service activities are those transformation services performed by TC Facility Staff on a research project, at the request of an Internal Danforth User or an External User, whether those services are performed by a lab technician or the Director.

If full-service transformation services are desired by an External User, requesting that a TC Facility Staff member perform work that is for the benefit of the External User organization, then the work will be considered work-for-hire for purposes of copyright and intellectual property purposes, and hourly rates will be assessed in accordance with

the Rate Fee Schedule in effect at that time, based on the external organization entity type and the consulting services performed.

To obtain and complete the “**Full-Service Request Form**” to begin the process, please go to the TC Facility Web Page (address located under Section B(1)(a)). The Director will follow-up within 5 business days of receipt of the request form to discuss your needs and the contracting requirements and pricing options.

In the event the Director can accommodate the full-service request, and in the event chemical or biological materials will need to be transferred to the TC Facility to perform the services requested, the External User will be directed to complete the “**Material Transfer Request Form**” located at:

<https://www.danforthcenter.org/scientists-research/technology-transfer>

All chemicals and materials to be transferred to the TC Facility will include any import/export permits/licenses and all fees related thereto will be borne by the sender.

The Internal Danforth Users and the External Users understand that the Danforth Center is required to maintain a Chemicals and Biologicals Inventory of all chemicals and biological materials located anywhere within the Danforth Center property, in order to comply with its Occupancy Permit. A complete and thorough listing of materials being transferred to the Danforth Center is required when completing the Material Transfer Request Form to obtain prior approval. All shipping instructions for approved chemicals and biological materials into the Danforth Center will be strictly followed, as directed by the Director and/or the Safety Officer.

Please note that we strive to provide the best possible products and services that we can achieve for our Internal Danforth Users and our External Users; however we cannot guaranty any research outcomes when providing full-service transformation services, as there may be unforeseen circumstances that are beyond our

control that may prevent us from achieving a desired outcome, including matters related to natural disasters, power outages, etc. If the TC Facility research efforts have determined that the project goals are unattainable, the project will be terminated after consultation with the Internal Danforth User or the External User and a fee will be assessed based on the actual expenses incurred and fees generated on the project to date of termination.

3. COLLABORATIVE SERVICES

When Users collaborate with TC Facility Staff on specific research projects, with the goal of sharing expertise, or with the goal of having TC Facility Staff perform full-service research on any Users’ behalf, a sponsored research agreement between the parties is recommended.

Ownership of any intellectual property developed under a sponsored research agreement, using TC Facility Staff and facilities and/or equipment, will be pursuant to the terms of the sponsored research agreement, as negotiated by the parties.

Collectively, all External Academic and External Non-Academic Users (whether utilizing self-services, full services, or collaborative services at the TC Facility) will be referred to in these Policies and Guidelines as “**External Users**”.

B. Access to TC Facility

1. HOURS OF OPERATION:

- a. Normal operating hours of the TC Facility are Monday through Friday from 7 am to 6:00 pm. (“**normal hours**”). There may be exceptions to this schedule, for weather or special events, which will be posted on the Danforth Center website under the TC Facility Webpage as far in advance as possible:

<https://www.danforthcenter.org/scientists-research/core-technologies/tissue-culture-transformation>

- b. In order for an External User to obtain permission to utilize the TC Facility

outside the normal hours (“*night/weekend access*”), advance written permission must be obtained from the Director. Only experienced External User Staff members will be eligible to apply for night/weekend access to the TC Facility and only during Director-approved hours. No student or intern staff members of the External User will be granted night/weekend access unless accompanied at all approved times by an External User’s experienced staff member, upon Director’s written approval.

- c. Night/weekend use privileges may be granted by the Director to experienced Danforth Users with Badge access to the TC Facility who are at the graduate level or higher, with significant experience showing productive and competent use on the TC Facility equipment (“*Equipment*”).

2. BADGE ACCESS:

The Danforth Center utilizes secure access requirements throughout the Danforth Center, with specific access and use privileges granted via electronic badges (“*Badge*”) to certain Users of the Core Facilities based on completion of required training and job descriptions.

All access to the Danforth Center is controlled by Badge readers at the doors, with separate electronic permissions granted uniquely to each Badge holder that is granted access to the Core Facilities.

Badge access will be granted to Users of the TC Facility only upon the written recommendation of the Director (submitted to the Security Officer). No Badge will be issued for access to the TC Facility until the training requirements described in paragraph B(4) below have been successfully completed.

The TC Facility is monitored through camera surveillance and periodic in-person visits to the TC Facility by Danforth Center’s security personnel. Therefore, it is important that all

Users wear their Badge at all times.

No Users with access to the TC Facility may share their Badge with any other person.

Contact the Director concerning lost or forgotten Badge ID cards.

The Badge must be returned to Director when the User’s access rights expire or are terminated.

3. COMMON AREA ACCESS AVAILABLE TO EXTERNAL USERS:

Specifically as to the External Users of the TC Facility, Badge access includes the use of the Danforth Center Café, bathrooms, hallways, stairways, elevators, and the Building A Lobby. All other common areas at the Danforth Center, including the conference rooms, lounge areas, fitness center, recreation areas, and other common spaces are dedicated to and reserved for Danforth Users only.

4. TRAINING REQUIRED FOR TC FACILITY BADGE ACCESS

a. **TC Facility Orientation Training**

TC Facility Staff will provide TC Facility Orientation Training to all Self-Service and Collaborative Service External Users and Internal Danforth Users, in addition to all other Danforth Users who have requested Badge access to the TC Facility (“*Orientation Training*”). Successful completion of Orientation Training is required prior to the Director granting any User a Badge access to the TC Facility and prior to the Director granting any User the privilege of operating the TC Facility Equipment.

Orientation Training will provide hands-on instruction as to proper use of the TC Facility Equipment, including a review of the TC Facility Policies and Guidelines.

External Users take sole responsibility for damages caused from improper operation of TC Facility Equipment. Use of the TC

Facility Equipment is fee-based and must be properly scheduled. A separate document entitled “**Equipment Scheduling and Use Policies**” is posted on the TC Facility Web Page listed in B(1)(a) above, as a reference sheet to the information received in Orientation Training, which outlines the requirements and policies associated with equipment scheduling and use.

Attendance at Orientation Training is on a space available basis for each Training class. It is recommended that External Users contact the Director to schedule their staff for class as soon as possible after they are aware of the anticipated start date under their Use License Agreement to avoid any delays. (Please see the “**External User Program**” posted on the Danforth Center website under the TC Facility Webpage listed under Section B(1) above for particulars regarding becoming an External User.)

b. Lab Safety Training

All Users requesting Badge access to the TC Facility will be required to attend and successfully complete the Lab Safety Training 4-hour class prior to accessing or utilizing the Equipment in the TC Facility.

Attendance at Lab Safety Training is on a space available basis for each Training class. The Director will coordinate with the Safety Officer to schedule External Users’ staff for this class. The Lab Safety Training class is offered periodically at a minimum of one time per month, but can be offered more frequently on an as-needed basis upon advance notice.

In the event Badge access to the TC Facility is needed sooner than a Lab Safety Training class can be scheduled, the Director can allow temporary Badge access to the TC Facility based on an online Refresher Training protocol, utilizing PowerPoint presentation modules that cover laser, radiation, chemical safety,

emergency protocols and the plant growth facility safety training, with quizzes at the end of each module. A score of 80 or above is required to pass and obtain a Temporary Badge. This does not replace the 4 hour Lab Safety Training class, as that will still be required to obtain a non-temporary Badge to access the TC Facility.

C. Lab Safety and Clean-up

All TC Facility users are expected to follow the “**Lab Safety and Clean-Up Policies**,” posted on the TC Facility Web Page noted in Section B(1)(a) above, in addition to the safety policies provided to each User during Lab Safety Training presented by the Danforth Safety Office.

D. Facility Tours of User’s Guests

Whenever a User desires to host a tour of the Danforth Center and/or the TC Facility for their family, friends, business associates, investors, etc. (“**Tour Guests**”) certain requirements must be met prior to any Tour Guests being allowed access to the Danforth Center or the TC Facility. Any User desiring to host a tour for their Tour Guests must review the policies and requirements contained in the “**Visitor Tours Hosted by External or Danforth Users**” located on the TC Facility Web Page listed in B(1)(a), submit the proper paperwork referred to therein, and must ensure that the Tour Guests abide by those requirements.

E. Billing Questions

Questions regarding charges invoiced should be addressed to the Director.

F. Confidentiality & Intellectual Property

1. GENERAL INFORMATION:

The work environment at the Danforth Center falls under its status as a non-profit corporation and academic scientific research

institute and, as with most other academic research institutions, is one of free intellectual exchange and collaboration. However, in order to allow External Users to work within the Danforth Center facilities and to protect the confidential information and Intellectual Property of the Danforth Center Users and other External Users, all persons who access and use the Danforth Center facilities (whether Danforth employees, External User Staff, visitors or consultants) sign a confidentiality agreement.

Each External User of the Danforth Center TC Facility shall be responsible to adhere to their License Agreement confidentiality terms and will ensure that their employees also are bound by such confidentiality requirements. These Policies and Guidelines are not intended to limit the requirements of those Agreements.

2. VIDEOGRAPHY AND PHOTOGRAPHY:

- a. Videography is not permitted by any Users or Tour Guests anywhere on the Danforth Center property due to confidentiality rights of all of Danforth Center guests, employees and Users.
- b. Photography of plants and plant materials is permitted in limited scenarios, see Section D for particulars, but never allowed to be taken of plants or plant materials in growth chambers, testing equipment and greenhouse spaces that are being used by commercial companies or on which full-service work is being performed by Danforth Users. No photographs, nor any type of digital images, may be taken of any labels associated with plants or plant materials of any Users of the Core Facilities that may be located on the pots, sticks in the pots, or located on other plant material containers of any type.
- c. Photography of persons whether in conjunction with plant materials, in testing environments, or anywhere on the Danforth Center property may not be taken

without the person's explicit permission due to confidentiality and privacy rights.

G. Research Involving Materials Classified for National Security Reasons is Prohibited

Danforth Center's Policy prohibits Danforth Users and any External Users in any of the Labs or Core Facilities from engaging in research at the Danforth Center where the research involves materials that are classified for National Security reasons, including but not limited to activities of any research project that would include the possession, use, harvesting or manufacture of select agents or classified materials, as the same may be defined in federal regulations, including but not limited to, the ITAR, EAR and the USA Patriot Act.

It is the responsibility of all Users to know what materials are classified for National Security reasons. Some helpful links are provided under Section L-Related Documents below. If in doubt, please ask the Director for clarification to ensure no federal regulations are being violated at the TC Facility with regard to National Security.

H. Published Reports and Publications

All External Users of the TC Facility shall keep Director informed of the nature and progress of their work to ensure the Permitted Uses in their respective Use License Agreements are adequate for the research activities being conducted.

In the event any reports or articles are published based on research activities performed at the Danforth Center by External Users, those published papers shall include an acknowledgment of the use of the Danforth Center in such publications or research reports, which acknowledgement shall read:

"This work made use of the Donald Danforth Plant Science Center research facilities at St. Louis, Missouri."

External Users shall provide the Director with a copy of any publications which were based, in part, on research conducted through the use of the TC Facility.

In addition, proper credit shall be given as a contributor or inventor, as such credit may apply, to any Danforth User who provided a measureable contribution to any idea that is the subject of any published paper or patent application filed by External User when such Danforth User provided services requested by the External User on the research project that is the subject of such published paper or invention.

I. TC Facility User Rates

Rates are established for the use of all Equipment in the TC Facility by all Users requiring transformation services described in Section A above. Equipment use rates are subject to change and are reviewed and updated on an annual basis. In general, there is an hourly rate for:

1. Self-service use of the Equipment, billable in ½ hour increments.
2. General Lab Services for training and for assisted use of the Equipment by TC Facility Staff.
3. Full-Service transformation services provided by TC Facility Staff for specific research projects, which is provided on an availability basis, as determined by Director.

Consumable materials may be purchased by self-service External Users at this time; however, **as of December 31, 2017, this service will no longer be provided**, unless arrangements are made with the Director in advance. If arrangements are made, consumable materials utilized by External Users are billed at cost, plus a nominal administrative fee. This service is provided as a convenience to the External Users and availability of consumable materials requested by External Users is not guaranteed.

J. Amendments to these Policies & Guidelines

Amendments to these Policies and Guidelines will be posted on the TC Facility website with an email notification to the Authorized Representative of any External User, who will be responsible to ensure their staff members have been informed. Compliance with any amendments to these Policies and Guidelines shall be immediate for all matters as of the date stated in the notification.

K. Violation of these Policies & Guidelines

Violation by an External User Staff member of the confidentiality requirements contained in the External User's Agreements, shall be grounds to have the Director revoke access of that External User Staff member from the TC Facility, at the Director's sole discretion, which could also include revocation of Badge access to all of the Danforth Property, at the discretion of any of the Corporate Officers of the Danforth Center.

Violation of the prohibition on using materials classified for National Security reasons, unless a written exception is received, is grounds for an External User to have their Use License terminated and all such materials destroyed and External User removed from the TC Facility premises.

No Users with access to the TC Facility may share their Badge with any other person. A violation of this requirement is grounds for permanently removing Badge access and Equipment use privileges for External User Staff, and termination of employment for Danforth User Staff at the TC Facility.

If a User refuses to adhere to any of these Policies and Guidelines, or the Lab Safety Training protocols, whether such refusal is by action or word, such User may have their Badge permissions to access the TC Facility and use the Equipment revoked by the Director, or potentially having employment terminated if the User is a Danforth User. Reinstatement of any such individual User's access to the TC Facility, or authorization to use

any of the Equipment, shall be at the Director's sole discretion.

L. Related Documents

The Donald Danforth Plant Science Center strictly adheres to the federal import/export laws and requires any Users of the TC Facility to be knowledgeable and compliant with the regulations relating to their own materials possessed, used and the disposal regulations regarding the same.

The following links provide access to federal lists, regulations and acts and are not to be considered exhaustive or all-inclusive and are only provided as a sample of federal regulations Users should be aware of:

U.S. Munitions List ("UMSL") of classified materials, services and goods under the International Trade Agreement Restriction Act ("ITAR") (*see*, pp 475+ and 484+)

https://www.pmdtdc.state.gov/regulations_laws/documents/official_itar/ITAR_Part_121.pdf

U.S. Department of Commerce, Commerce Control List of classified materials under the Export Administration Regulations Act ("EAR") (*see*, pp 66-67)

<https://www.bis.doc.gov/index.php/document/regulation-docs/1561-ccl-categories-0-9/file>

USA Patriot Act list of select agents:

<https://www.selectagents.gov/SelectAgentsandToxinsList.html>

Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requirements re possession of select agents (*see*, Section 334 and 335):

<https://energy.gov/sites/prod/files/2014/03/f12/PL107-188.pdf>

US Dept. of Treasury, Office of Foreign Asset

Control for list of embargo/trade sanction countries:

<https://www.treasury.gov/resource-center/sanctions/Pages/default.aspx>

Animal and Plant Health Inspection Service ("APHIS") import regulations of foreign agricultural products into the USA by US Dept. of Agriculture:

https://www.aphis.usda.gov/publications/plant_health/2012/fs_imp_food_ppq.pdf

THE BELOW SIGNATORIES CONFIRM THAT THE TC FACILITY POLICIES & GUIDELINES HAVE BEEN READ, AN ELECTRONIC OR PAPER COPY HAS BEEN RECEIVED BY THE EXTERNAL USER AND STAFF, AND ALL PARTIES AGREE TO ABIDE BY THE SAME:

INTERNAL DANFORTH CENTER USER:

Printed Name: _____
Department Affiliation: _____
Date Signed: _____

EXTERNAL USER STAFF MEMBER:

Printed Name: _____
Organization Affiliation: _____
Date Signed: _____