

**CSC CHARTER &
PRINCIPAL
INVESTIGATOR'S
GUIDE**

Chemical Safety
Environmental Health and Safety
UNT Health
Fort Worth, Texas 76107

Chemical Safety Committee Registration form Submission, review and approval Process

Approval and Implementation

The Principal Investigator’s Guide to the CSC is hereby approved by the Institutional Biosafety Committee for the University of North Texas Health. This document shall apply to all UNTH Health personnel at UNTH Health facilities working with chemicals and toxin material. The details of this guide are developed to ensure regulatory compliance. This document is effective immediately and supersedes all previous editions.

This guide will be reviewed annually and updated as needed to ensure compliance with regulatory changes or changes in procedures.

Approved  _____

Dr. Katalin Prokai PhD
CSC Chair

Record of Changes

Change #	Date of Change	Change entered by	Description
1.	Oct 16, 2025	AS Brocard	New document

A. Background information

The Institutional Biosafety Committee at the University of North Texas Health has the responsibility to assure that all chemical/toxin safety activity meets federal law mandates, Public Health Service policy, and all accreditation expectations. The goal is to maintain a safe workplace, prevent environmental contamination and comply with federal, state and local requirements.

B. Responsibilities

a. Principal Investigator

- i It Is the responsibility of the PI to ensure that no work is started without final CSC approval of a registration form.
- ii It is the responsibility of the PI to submit registration form submissions in a timely manner to allow for proper review.
- iii It is the PI's responsibility to ensure that all their staff have read and understood the information in the CSC registration form prior to starting a project.
- iv It is the responsibility of the PI to identify research projects that may require CSC approval.
- v It is the responsibility of the PI to ensure that their registration is maintained up to date by submitting the needed amendments on time.
- vi All PIs must submit accurate, current, and complete hazard registrations including providing all pertinent supplemental documents (e.g. plasmid maps, SOPs, etc.).
- vii It is the PI and laboratory staff responsibility to report all incidents, exposures, spills to EHS.
- viii Follow all approved protocols and registration forms, maintain strict compliance with biosafety and biosecurity standards.

b. EHS Office

- i the EHS office will conduct a pre-review of all registration forms and amendments prior to their submission to the CSC and notify the CSC of administratively approved items.

c. CSC members

- i It is the responsibility of the CSC members to review new registration forms, amendments and renewals to ensure they meet regulatory requirements, the PI and staff have the needed knowledge and that UNT Health has the appropriate facilities and containment device to safely conduct the proposed research

d. CSC Committee

- i The CSC advises the VPR on policy matters concerning the protection of personnel from chemical/toxin materials that may be present in laboratory or clinical areas.
- ii The CSC shall also recommend guidelines relating to procedures and facilities used at UNT Health, including such matters as safety training and health surveillance.
- iii The CSC will offer its counsel to all UNT Health personnel regarding matters of chemical/toxin safety. The VPR may ask the CSC to inform the community about developments in the general area of chemical safety.

C. CSC membership

The CSC membership shall consist of a minimum of five (5) persons.

The VPR appoints the members of the CSC on a 3year basis. Members are eligible for reappointment to multiple consecutive terms. The CSC should have a representative from the Safety Office, a representative from the Office of Research Compliance and a representative from DLAM.

D. Meeting Schedule

The CSC operates in accordance with its approved charter and holds monthly meetings on the 3rd Thursday of each calendar month with exceptions for holidays. The meeting schedule is available on the [Chemical Safety webpage](#).

The CSC will keep meeting minutes; these minutes will be approved at the following month's meeting.

E. Material requiring CSC notification/approval

PIs are required to notify the CSC that they possess or plan to use the following material:

- Chemical classes
 - Pyrophoric
 - Alkali Metals
 - Metal-carbonyl complexes
 - Water Reactive: Hydrides & Acid Chlorides
- Experiments
 - Nitration
 - Diazotization
 - Ozonolysis
 - Diazomethane formation
 - Metal-catalyzed Carbonylation
 - Hydrogenation
 - Lachrymator formation

For a list of chemical/toxins materials that require the submission of a hazard registration, please contact EH&S.

F. CSC Submission forms

All submission forms need to be submitted to the CSC at Safety@unthsc.edu and copied to Dr. Maya Nair, PhD RBP (ABSA) at maya.nair@unthsc.edu

a. Initial/renewal registration forms

An Initial registration form is submitted when a project with new chemical/toxin material listed above is ready to be initiated.

A renewal registration form is submitted three (3) years following approval of an initial registration form, indicating that the project is still on going.

b. Amendments to registration form

An amendment or a resubmission to an approved registration form must be submitted when the following changes are needed:

- changes to the project objectives
- changes to the process
- adding/removing listed material
- adding/removing listed personnel
- changes in the use/storage location
- the purchase or acquisition of new chemical/toxin listed in section E
- providing chemical/toxins listed above to another investigator on or off campus
- arranging for visiting researchers to work in your laboratory
- if minors will be working in their respective laboratories - refer to UNT Health's policy on minors on campus

The EHS Office will review the submission and determine if the amendment requires CSC evaluation or if the original risk assessment covers the proposed changes.

G. Registration form time frame

a. Approval time frame

All registration forms are approved for a three (3) year period from the month of the CSC approval. Approved amendments do not change the date of the original registration approval.

b. Expiration time frame

Prior to the expiration date, PIs are required to resubmit an updated registration form for full CSC review. The PI will receive a written renewal notice, from the EHS office, 90-days prior to the registration expiration date. The EHS office may send out additional reminders as a courtesy.

PIs may request from the CSC an extension to the renewal of a registration, this request must be made in writing to the CSC and approved prior to the expiration date of a registration.

In the case of a renewal not being approved before the registration form's expiration date, the PI will be notified in writing that **no procedures** may be performed until the registration form is approved.

The CSC will be notified that the registration form has expired without securing a renewal approval.

Note: All work listed on an expired protocol must immediately stop, unless the CSC has granted a written exemption.

It is recommended that the PI submit a renewal protocol at least two (2) months prior to the expiration date.

c. Submission time frame

Registrations and amendments requiring full CSC review, must be submitted to the CSC three (3) weeks prior to the meeting to allow time for a pre-review by the EHS office and responses.

Registrations and amendments that are not received in time, may be deferred to the following months CSC meeting, delaying the project.

d. Response to the CSC time frame

The PI must respond to CSC request for modifications within three (3) months of the CSC meeting. If the PI is non-responsive for three (3) months the EHS office will contact the PI, indicating that if no response is received within two weeks, the study will be withdrawn from further CSC consideration. If the PI wishes to pursue this study after it has been withdrawn, a new registration form application will need to be submitted for review.

H. CSC review process

a. Pre-review

When a registration form or amendment is submitted to the CSC, the EHS office will conduct a pre-review of the document to ensure all the needed information is provided. The EHS office will inform the PI of any changes that are needed prior to submitting the document for CSC review and approval. If a PI fails to respond to the pre-review comments, the protocol/amendment will be submitted to the CSC as is. This may lead to significant changes needed to secure approval and lead to delays in the approval of the document.

b. CSC review

Registration forms are sent to two (2) designated CSC members for review and comments. These CSC members will present the proposed project and their comments to the rest of the CSC members. All CSC members are provided with all registration forms to be reviewed and discussed at the meeting, and they will also be given the opportunity to provide comments on the project.

The registration form will be then put to vote with the following options:

- a. **Approved:** Meets all standards and is approved in the current form by full committee. No corrections or modifications are needed. The PI will be notified of the approval.
 - b. **Requires Modification to Secure Approval (RMSTSA)**
 - i. Modifications required to secure approval by administrative review: This final approval is done by the EHS office after the requested modifications have been received from the PI.
 - ii. Modifications required to secure approval by designated review (DR): This final approval is done by designated CSC reviewers after the requested modifications have been received from the PI.
 - iii. Modifications required to secure approval by full committee review: This approval requires the registration form, following the required modifications have been completed, to be reviewed and approved at the next month's convened CSC meeting.
- Note:** at any time, the EHS Office or a DR can request the registration form to be brought back to the Full CSC committee for review and approval.
- c. **Withhold Approval:** The reasons for approval to be withheld are given to the PI who may submit a revised registration form for review at a subsequent meeting.

c. EXPEDITED REVIEW by DESIGNATED MEMBER REVIEW

A PI can request an Expedited Review of a registration. A formal request with supporting justification must be sent to the CSC. The CSC chair in consultation with the EHS Office will approve the expedited review process.

Expedited Review is when an CSC registration form is reviewed at a time other than during a full committee meeting. A minimum of 5 CSC members is needed to review and approve the registration form.

Expedited reviews can be done via email.

The registration form approval will be recorded in the following CSC minutes.

d. Administrative approval

The EHS Office has been granted by the CSC the ability to administratively approve minor amendment to registration forms. This reduces the approval time of the amendment.

All administrative approvals are recorded in the following CSC minutes.

Administrative approval includes:

- minor changes to the process
- removing listed material
- adding new cell lines if similar ones are already included in the registration
- adding/removing listed personnel
- changes in the use/storage location
- providing UNT Health regulated chemical/toxin materials to another investigator on or off campus
- arranging for visiting researchers to work in your laboratory
- if minors will be working in their respective laboratories - refer to UNT Health's policy on minors on campus

The EHS Office has the authority to call any amendment to a full CSC board review if they deem it necessary to ensure proper review process.

e. **Conflicts of Interest**

CSC members must recue themselves from the review and vote of a registration if they have a conflict of interest. These include but may not be limited to:

- Listed as a PI, Co-PI or staff on a protocol
- Institutional conflict of interest
- Conflicts of commitment
- Individual conflicts
 - Financial
 - Competing

f. **PI notification**

Following the CSC meeting the PI will be notified in writing of the outcome of the vote.

- For Registration forms that have been approved the PI will be provided with an approval letter from the CSC and work can commence/continue.
- For Registration forms that require modification to secure approval or withhold approval, the PI will be provided with the required changes to be addressed. The PI will email the updated registration form to EHS Office for review and processed based on the CSC decision.

Note: No work can commence or continue (renewals, amendments) without an CSC approval letter.

I. Minutes

The CSC coordinator will keep minutes of the CSC meetings. These minutes will include the following information on each reviewed registration.

- PI name
- Title of the project
- Chemical/toxin
- Brief description of the project
- Recommendations from the CSC of changes needed to secure approval if applicable
- The vote results

The minutes will also include the following information

- Registrations that have been administratively approved
- Registrations that have responded to CSC recommendations and have been approved
- Incidents that have occurred
- Non-compliance situations
- General information presented to the CSC for discussion, input or training.

The minutes will be reviewed and approved at the following convened full meeting.

J. Closing of registration forms

- a. A PI at any time may close a registration form by submitting an amendment form to close the registration form. Once a registration form is closed, it cannot be re-opened. If a PI wishes to reinitiate a closed study, a new registration form will need to be submitted to the CSC for review.
- b. All registration forms expire at the three-year expiration date. If the study continues, the PI must submit a renewal registration form for the CSC to review prior to the expiration date. This renewal is handled as a new submission.
- c. The CSC may reserve the right to administratively close out registration forms in which the PI is no longer able to fulfill the role as PI, and there is no one available to take the PI's place.
- d. The CSC will be notified of closed registration form at the following convened meeting.

K. Non-Compliances with the CSC

a. Failure to register with the CSC

Any PI who fails to register the use and/or storage of applicable chemical/toxin materials with the CSC will be reported to the EHS Office.

PIs who fail to register these materials following a request from the EHS Office will be immediately reported to the Director of EH&S, the CSC Chair, the VPR and Department Chair.

b. Suspension of registrations

Following non-compliances with safety regulations and UNT Health policies, the CSC Chair and/or Vice Chair have the authority to temporarily suspend all approved CSC registrations at which time the CSC will submit a suspension letter to the PI.

A copy of this letter will be sent to the VPR, PI's department Chair, and the Director of the Director of Office of Research Compliance.

To obtain or regain CSC authorization to use applicable chemical/toxin material, the PI will be required to submit all pertinent registrations forms and all applicable supplemental documentation to the EHS Office.

This information will be provided to the CSC, at the next scheduled meeting, for evaluation.

The CSC may, at their discretion, authorize/re- authorize the PI's project, authorize the PI's project under specific/defined conditions, place the PI's hazard registration(s) under continued suspension, or terminate the PI's registration(s).

Additionally, the Director of EH&S and the CSC Chair may recommend to both the VPR appropriate action if an investigation reveals significant violations.

L. References

- Chemical manual
- Occupational Safety Manual