



## **Institutional Biosafety Committee**

### **How to Submit a New IBC Protocol Registration in DASH Research Safety**

This document will walk you through the steps of submitting an **IBC protocol** registration in **DASH Research Safety**, the new IBC submission system of the University of Tennessee. Please contact the Office of Research Integrity at [ibc@utc.edu](mailto:ibc@utc.edu) if you have any problems or questions about the process.

**The following categories of experiments require physical containment safeguards and levels of oversight that are not currently available at UTC. Contact the IBC if your activities will involve one or more of these categories:**

- NIH Category III-A: Studies involving the deliberate transfer of drug resistance to microorganisms (not known to acquire the trait naturally) that can compromise the use of the drug to control the microorganism and its disease in humans, veterinary medicine, or agriculture.
- NIH Category III-B: Cloning genes that encode for toxin molecules with LD-50<100 nanograms/kg body weight. Examples: botulinum, tetanus, diphtheria toxins.
- NIH Category III-C: Transfer of recombinant DNA, or DNA and RNA derived from recombinant DNA, into one or more human subjects.
- Large-scale experiments (e.g., involving more than 10 liters of culture per container).
- Experiments involving Risk Group 3 or 4 agents/toxins.

#### **WHO IS SUBMITTING THIS PROTOCOL REGISTRATION?**

The Principal Investigator (PI) (research protocol), Lead Instructor (teaching protocol) or Faculty Advisor (student project) is required to complete and submit the IBC protocol registration within DASH Research Safety. Only UTC faculty and staff can be listed as a Principal Investigator (PI) within the smart form; students cannot be listed as a PI within the smart form nor submit an IBC protocol registration.

## BEFORE STARTING AN ONLINE SUBMISSION

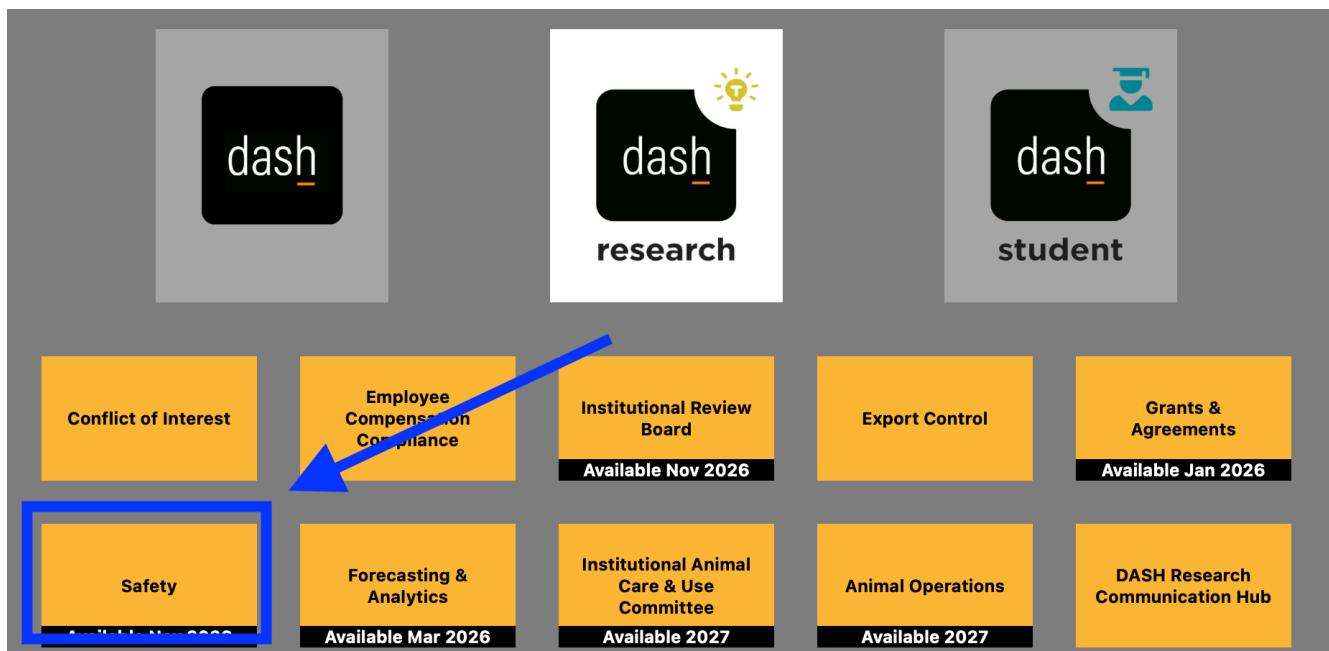
**CITI TRAINING:** All protocol team members should take CITI training, or check their training certificate status. <https://www.utc.edu/research/research-integrity/biosafety/training>. If training isn't complete at the time of protocol submission, it will need to be completed before IBC approval.

**STUDENT PROTOCOL TEAM MEMBERS:** **To list UTC students on a protocol, they must be 'in' the DASH Research system.** Students who are not already employees as a student worker, GA, etc., must be added to the DASH Research system manually. If you cannot find a student while filling out your protocol, contact the Office of Research Integrity for assistance (ibc@utc.edu).

## Login to DASH via the homepage

<https://dash.tennessee.edu/home>

Navigate to DASH Research, then to the Safety tile.



## FILLING OUT THE SMART FORM

### Create a Safety Submission

#### **CREATE SAFETY SUBMISSION:**

From the Dashboard: Click “Create,” Select “Safety”, then “Create Safety Submission”

OR

From the Safety Tab: Click “Create Safety Submission.”

This process will open the smart form for submitting your IBC protocol registration.

**You must complete and save the “Basic Information” page before a new protocol will be created in the system.**

**NOTE:** all questions with a red asterisk are required for every submission.

#### **Basic Information**

**Q1: SELECT ADMIN OFFICE:** **Select UTC-Biosafety**

**Q2: TITLE OF PROTOCOL:** Enter the full title of the protocol, making sure the title is the same as on any funding documents, if applicable. If the protocol is for a course, include course subject, course number and title of the course (e.g. BIOL 4220 Principles of Microbiology Laboratory).

**Q3: SHORT TITLE:** This can be the same as the full title (above) or shorter; it will be the title that identifies the protocol in DASH Research Safety for your reference. Keep it shorter than 50 characters.

**Q4: SUCCINCT DESCRIPTION...:** Include information describing the proposed experiments, making sure to answer the four subsidiary questions (goals of research, why are goals important, proposed experiments and how the experiments achieve these goals).

## Basic Information

**Q5: SELECT APPROPRIATE SAFETY REVIEW:** Select “Biosafety” for this question.

**Q6: PRINCIPAL INVESTIGATOR:** This will auto-populate to the name of the person completing and submitting the protocol. Make sure it shows the correct name for the PI, Lead Instructor or Faculty Advisor.

**NOTE:** The only person who can submit the protocol is the person who is listed as the PI.

**Q7: DESCRIBE THE PROPOSED EXPERIMENTS IN DETAIL:** Be sure to include information regarding the experimental design, techniques used, and the use of each agent/toxin/microorganism. Also include manipulation/analyses of materials transformed, transfected or transduced with rDNA vectors. The IBC uses this information to assess appropriate safety procedures for the proposed activities. Don’t forget to include information regarding the transport of biological agents between labs or between buildings on campus.

**Q8: TYPE OF PROTOCOL:** Select all that apply.

**CONTINUE:** When you click the “Continue” button, your protocol is assigned a protocol number, in the format “SPROTO202500000123” and you will be able to continue adding information pertinent to your protocol. Your protocol is saved at this point, and you can come back to it to make changes before it is submitted. It is NOT submitted to the IBC until a later step. **Clicking “Exit” will take you out of the smart form and back to the main submission page, without saving information.** **“Save”** will save items on the page.

## Protocol Team Members

**Q1: ID EACH ADDITIONAL PERSON....:** Select “+Add” to add any UTC students, faculty or staff involved in the protocol. The PI listed on the first page of the smart form will automatically be included on the protocol team: **DO NOT** add the PI on this page. If you need to remove a UTC student, faculty or staff from the list, click the “X” on the right side of the table.

**NOTE:** Check all the roles that apply for that protocol team member and if they are involved with procedures.

**NOTE:** Protocol team members can view and edit the submission while it is in the pre-submission state once they are added to the protocol. **However, only the PI can submit the protocol registration.**

**NOTE:** If you cannot find the name of the student you want to add to the protocol, reach out to the Office of Research Integrity for assistance.

**Q2: TEAM MEMBER TRAINING:** After you have added all UTC protocol team members, click “Save”. This will update the CITI Training for each UTC person on the protocol. The IBC Office will confirm if the required CITI Training has been completed.

**Q3: EXTERNAL TEAM MEMBER INFORMATION:** To add an external team member (someone not affiliated with UTC), click the “+Add” button. In the “Title” field, enter the person’s name.

You are required to upload a document for this person. The IBC recommends uploading documentation of completed training.

Click “CONTINUE” to move to the next page.

## Funding Sources

**Q1: IDENTIFY EACH ORGANIZATION SUPPLYING FUNDING FOR THE PROTOCOL:** If your protocol is associated with any funding, add your funding source here (external or internal). Click the “+Add” button to search for funding sources. For internal UTC funding, select the Department the funding is coming from.

*Helpful Hint:* Use the percent sign “%” to help filter your search. For example, to search for a URACE SEARCH Award, filter by “%student research”. URACE is represented as “475005-Student Research”.

**If you cannot find your funding agency on the list, contact the Office of Research Integrity for next steps.**

*Sponsor’s Funding ID:* Include the external sponsor’s funding ID number, if applicable.

*Grants Office ID:* If funding is from an external funder, include the Cayuse Award Number in this space. If funding is internal, include the name of the award (e.g. SEARCH Award).

*Attach Files:* Be sure to attach a copy of the funding proposal here. The IBC reviews the proposal with the protocol for congruency.

If your project does not have funding, simply click “**Continue.**”

Click “**CONTINUE**” to move to the next page.

## Biosafety Summary

**Q1: SELECT ANY ITEMS INVOLVED IN THE PROTOCOL:** Select all that apply. Once saved, each of the selected categories will generate a new page for you to complete.

**NOTE:** Activities that involve the following categories require physical containment safeguards and levels of oversight that are NOT currently available at UTC. If your activities involve one or more of these categories, contact the IBC:

- Select Agents or Toxins
- Human Gene Transfer/Human Clinical Trial
- Gene Drives/Gene Drive Modified Organisms

## Biosafety Summary

Click “CONTINUE” to move to the next page.

## Agents, Toxins & Microorganisms

There are several categories from the Biosafety Summary page that will generate a page within this section. However, the questions that must be answered are all very similar, if not the same, for each one.

**Q1: LIST THE TYPE/AGENT/MICROORGANISM THAT WILL BE USED:** Click the “+Add” button to add an item to the protocol.

*Agent:* Click on the ellipsis to open a new window. From here you will find the agent you want to add. Use “%” as a wildcard to find your agent. For example, to find *Escherichia coli*, type “%coli”.

**NOTE:** Use the full scientific name of the organism, if applicable.

If you cannot find the biological agent on the list, contact the Office of Research Integrity for next steps.

*Biocontainment Level:* Select the applicable biocontainment level for that agent.

*Describe the use of the agent:* **This information should already be provided within Q7 on the Basic Information page. To streamline the submission and review process, just indicate the information is provided within this earlier question.**

*Strain:* Make sure to indicate the strain of the organism, if applicable.

*What is the source/origin of the material?:* Is the material originally from a human, another animal? If so, what organism is it derived from?

*Storage locations:* Indicate all locations (Bldg and Room) in which this agent is stored.

## Agents, Toxins & Microorganisms

*Usage locations:* Indicate all locations (Bldg and Room) in which this agent will be used.

*Commercial source:* If you are purchasing the agent from a commercial source, indicate the vendor and catalog number here.

Answer all other questions to the best of your ability within this pop-up window and within the page you are working on.

**Click “CONTINUE” to move to the next page.**

The “Biohazards” page is a summary of the agents you have just added to the protocol. Review and confirm the information is accurate.

## Recombinant or Synthetic Nucleic Acid Usage

**UTC facilities cannot currently support activities that fall under Section III-A, III-B or III-C of the NIH Guidelines, large-scale experiments or those involving RG 3 or 4 agents/toxins.**

**DOES RESEARCH WITH rsNA INVOLVE THE USE OF:** Select the category in which you think the activities of this protocol would fall under. Select all that apply. The IBC will make the final determination of the category.

**NOTE:** UTC’s IBC requires full approval of the proposed activities PRIOR to their initiation, regardless of the *NIH Guidelines* category.

**NOTE:** The *NIH Guidelines* can be found on UTC’s IBC website:

<https://www.utc.edu/research/research-integrity/biosafety/bylaws-policies-and-procedures>

**Click “CONTINUE” to move to the next page.**

## Recombinant or Synthetic Nucleic Acid Work Description

Within this page, you will provide information regarding the host-vector systems, procedures, proteins produced, genes expressed, etc. Include detailed information to ensure the IBC can assess appropriate risk levels for the proposed activities.

**Q2: DESCRIBE THE PROPOSED EXPERIMENTS IN DETAIL...** *This information should already be provided within Q7 on the Basic Information page. To streamline the submission and review process, just indicate the information is provided within this earlier question.*

**Q12: COMPLETE THE FOLLOWING:** Fill out the required questions regarding each vector/gene being used. If your activities **DO NOT** involve using a vector (e.g. using oligos and not inserting them into a living cell), fill out the table using the following information:

*Sequence Name:* List the name of the oligo you are using.

*Function of the Gene, cDNA, or Sequence (insert):* Include a short description of the purpose of the oligo.

*Purpose:* If none of the options apply, just select one.

*Species of Gene/Sequence of Origin:* Within this space indicate that you had to select an option for the question above, but this purpose does not apply to the proposed activities.

*Does gene/insert encode any of the following?:* Choose the most appropriate answer.

**Click “CONTINUE” to move to the next page.**

## Risk Group and Containment Practices

**Q1 & Q2: RISK GROUP & BIOCONTAINMENT LEVELS:** For each of these questions, indicate the risk group level and the biosafety containment practices that will be used in the proposed activities.

**Q3: INDICATE ANY APPLICABLE BIOCONTAINMENT TECHNIQUES,...:** Describe any control measures that will be used. This would include equipment used to contain the biologicals, specifics regarding where tasks will be conducted, measures to prevent aerosol exposure, required vaccinations, etc.

Click “CONTINUE” to move to the next page.

## Exposure Assessment and Protective Equipment

**Q1: DESCRIBE CONSEQUENCES OF EXPOSURE OR RELEASE OF AGENTS TO HUMANS, ANIMALS AND PLANTS:** Describe the consequences of accidental exposure to each agent listed in the protocol. This includes assessing effects on personnel, community and the environment. You will also need to include potential exposure routes for personnel, associated symptoms of exposure, steps taken to ensure the safety of exposed personnel and if treatment options are available (if applicable).

**Q2: INDICATE THE PERSONAL PROTECTIVE EQUIPMENT THAT WILL BE USED:** Select all that apply.

Click “CONTINUE” to move to the next page.

## Dual Use Research of Concern

**UTC facilities cannot currently support activities that fall under the category of Dual Use Research of Concern. Use the following information to complete this page.**

**Q2: DUAL USE CATEGORY 1 EXPERIMENT CATEGORIES USED IN THIS RESEARCH:** For all protocols, Select “**None of the above**”.

**Q5: EXPLAIN WHY YOU BELIEVE THIS PROTOCOL IS OR IS NOT DUAL USE RESEARCH OF CONCERN:** For all protocols, insert the following text: **None of the biological agents and toxins specified in Section 4.1.1 of The United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential are used in this protocol.**

Click “CONTINUE” to move to the next page.

## Waste Management

**Q1: DESCRIBE THE PROCESS FOR HANDLING AND/OR DECONTAMINATING**

**BIOLOGICAL WASTE:** Include information that includes how biological material will be decontaminated or inactivated, the types of waste generated and required treatment before disposal. The IBC will also want to know the disposal method for waste generated:

- **BGE:** red BHW bag, BHW box, Holt 108 for pick-up by EHS
- **Chemistry/Physics:** red BHW bag, BHW box, Grote 417 for pick-up by EHS
- **Chemical Engineering:** red BHW bag, BHW box, kept in lab for pick-up by EHS.

**Q2: AUTOCLAVE LOCATION:** Indicate the location of the autoclave that will be used for this protocol.

## Waste Management

Click “CONTINUE” to move to the next page.

## Supporting Documents

Attach any additional documents that are necessary for the protocol registration and will be helpful for the IBC review.

**Click “Finish” to save your progress and exit the form. This does NOT submit the form.**

Notice your protocol number and short title appear at the top of the protocol workspace. Under the protocol information, you’ll see a flow chart that shows you where your registration is in the submission process. At this point, it should still say “Pre-submission”, as shown below.



**IMPORTANT! You must click “Submit” on the protocol workspace before your protocol registration is submitted to the IBC.**

Pre-Submission

Next Steps

[View Protocol](#)

[Printer Version](#)

[Submit](#)

The protocol will move to the Specialist Review stage of the process. Monitor your email and the DASH Research Safety protocol workspace for requests for clarification or other updates to your IBC protocol registration. You should see a graphic illustration of the workflow showing your protocol is in the Specialist Review stage, as shown below:



## AFTER SUBMISSION

**REQUEST FOR CLARIFICATION:** You may receive a request for clarification from the IBC Administrator via a system-generated email notification which will link back to your protocol workspace. Revise the protocol and reply to the request for clarification within the system. Please refer to the guidance document for responding to requests for clarification on the IBC website.

**APPROVAL:** At the time of approval, the IBC office will send you an approval letter via a system-generated email notification. Activities associated with this approved protocol may now begin. Changes to a protocol after approval can only be made via an amendment/CR submitted in DASH Research Safety. See our guidance document for assistance in the submission process.

Protocols are valid for up to three years from the approval date. Principal Investigators are required to complete a continuing review (formally called an annual update) each year within DASH Research Safety up until the 3-yr anniversary of the approval date. To renew the protocol, PIs will submit a de novo protocol to the IBC for review. Failure to submit a continuing review or a de novo protocol by the deadline specified will result in the protocol lapsing or completed, respectively. No activities may take place under a lapsed or completed IBC protocol.