



# RESPONSIBLE RESEARCH

TEXAS TECH  
Research & Innovation

## INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING MINUTES

27JUN25

1100 – 1300

Hybrid: ESB2 102A; Teams

\*Blue hyperlinks are active in this document.

### Members Present:

Member	Present (✓)	Member	Present (✓)	Member	Present (✓)
S Presley	<input checked="" type="checkbox"/>	G Huddleston	<input checked="" type="checkbox"/>	A Shin	<input type="checkbox"/> absent w/ notice
C Reinoso Webb	<input type="checkbox"/> absent w/ notice	R Maloney	<input checked="" type="checkbox"/>	S Shringi*	<input type="checkbox"/> absent w/ notice
C Brelsfoard	<input checked="" type="checkbox"/>	B Mount <sup>◇</sup>	<input checked="" type="checkbox"/>	E Tumban*	<input checked="" type="checkbox"/>
T Brooks	<input checked="" type="checkbox"/>	G Patil	<input checked="" type="checkbox"/>	H Zhang	<input checked="" type="checkbox"/>
K Buxkemper	<input type="checkbox"/> absent w/ notice	C Phillips	<input type="checkbox"/> absent w/ notice	M Roe	<input checked="" type="checkbox"/>
C Freeman	<input checked="" type="checkbox"/>	S Scoggin	<input checked="" type="checkbox"/>	A Young*	<input type="checkbox"/> absent w/ notice
G Henniger <sup>◇</sup>	<input checked="" type="checkbox"/>	A Shakya	<input type="checkbox"/>	A Matviko*	<input type="checkbox"/> absent w/ notice

Member roles and expertise are available on the IBC homepage: <https://www.depts.ttu.edu/ehs/academicsafety/icc/ibc.php>

\* Virtual attendance; <sup>◇</sup> Community Member; <sup>^</sup> Alternate Member

**Others Present: none**

**The Chair called the meeting to order at 1113.**

### I. IBC Functions pertinent to the NIH Guidelines

#### 1. Standing Business

##### a. Review of previous minutes

**Minutes from the meeting on 30MAY2025 were reviewed; no corrections were noted. A motion to approve the minutes as written was made and seconded. The motion carried without abstention or opposition.**

**Approve: 13**

##### b. Final Application Review and Approval

*NOTE: Applications presented for approval have been electronically reviewed in the Cayuse Hazard Safety module prior to the meeting. All requested clarifications and deficiencies, including training deficiencies, have been corrected or completed prior presentation for approval at the committee meeting. A full committee review was not requested by any member during the electronic review process. The final application is presented for a final review in the meeting prior to the vote. Refer to attached summary sheets for project details – only voting information is below.*

##### i. IBC-2025-1193. Yim, Sun Hee. Environmental Impact on Aging.

**No additional clarifications for approval were brought forth upon final review. A motion to approve the protocol as presented was made and seconded. The motion carried without abstention or opposition.**

**Approve: 13**

- ii. IBC-2024-1166. Gollahon, Lauren S. The Role of [REDACTED]<sup>1</sup> in Mitigating Leaky Gut in Bovine.

**No additional clarifications for approval were brought forth upon final review. A motion to approve the protocol as presented was made and seconded. The motion carried without abstention or opposition.**

**Approve: 13**

- iii. IBC-2025-1208. Tran, Son. Development of New Gene Editing Technology in Crop Plants.

**No additional clarifications for approval were brought forth upon final review. A motion to approve the protocol as presented was made and seconded. The motion carried without opposition. One member abstained noting conflict of interest.**

**Approve: 12  
Abstain: 1**

c. Full Committee Reviews

- i. None.

**A full committee review was not requested for any applications this month.**

2. NIH-related business

a. New Business

- i. [NIH Template for Minutes](#) regarding NIH Notice NOT-OD-25-082: Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

**The BSO present the NIH-OSP Document entitled “NIH Guidance: Institutional Biosafety Committee Meeting Minutes *Template and Points to Consider*” to the committee for discussion and review. The following was brought to the attention of the committee:**

- **PI names and titles of projects cannot be redacted; member names cannot be redacted.**
- **Information available on public facing pages cannot be redacted.**

**Additional points to consider included:**

- **Role and or involvement of General Council (GC) in IBC business and posting of minutes: 1) Educate, 2) directly involved them, 3) have legal review and approve prior to posting, or 4) make no changes current operations.**

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<sup>1</sup> Redacted to protect intellectual property.

- The committee determined that GC or legal from within the Office of Research Services (ORS) should be included in IBC meetings and will defer approved minutes to the GC as needed, particularly to review redactions.
- Involvement of MTA or Commercialization Office
  - The committee agreed to involve Commercialization as needed in review of minutes prior to posting to consult on intellectual property in protocol summaries.
- Use of footnotes to indicate why information was redacted.
  - The committee agreed to the use of footnotes to describe redacted material.
- Delineating NIH-responsibilities from Institutional responsibilities.
  - A motion to delineate NIH and Institutional responsibilities within meetings going forward was made and seconded. The motion carried without abstention or opposition.

**Approve: 13**

ii. Protocol Summary Template Review for New Minute Requirements

**The BSO presented a Protocol Summary example to meet the recommendations in the NIH template mentioned in agenda item 2.a.i above. Committee members expressed concern for compromising intellectual property, as well as PI safety and facility security for in vivo work.**

iii. [NIH](#) and [USDA](#) Notices regarding compliance with the [Executive Order: IMPROVING THE SAFETY AND SECURITY OF BIOLOGICAL RESEARCH](#).

**The NIH and USDA notices requesting information in regard to compliance with [Executive Order 14292](#) were provided to the committee for review. The BSO updated the committee with on the effort to provide information by the deadlines in the notices to the respective agencies and the collaboration with the ORS to collect necessary information from Principal Investigators (PI) to comply. The BSO asked faculty to extend a thank you to all their peers for the cooperation to complete the declaration form on such short notice during the summer months.**

iv. PI Declaration Form regarding Gain-of-Function research pertinent to the NIH and USDA notices.

**Members were provided with the PI Declaration Form which university faculty that currently or previously had held IBC protocols received electronically for compliance with the notices in 2.a.iii above. Members were also provided with a copy of an email the IBC Office received from a concerned faculty member regarding the declaration form. The BSO asked for additional comments from**

**the committee regarding the email. The committee felt the reply from the IBC Office was sufficient.**

**A member asked the BSO about continued or future use of the declaration. The BSO indicated that continued or future use of the declaration form is undetermined and will be assessed when the new policies to comply with Executive Order 14292 are released.**

**b. Open Business**

**i. PI Noncompliance – update and next steps**

**The committee was informed that Dr. Yim had met the requirements to resolve her noncompliance event. A motion to close the matter was made and seconded. The motion carried without opposition; one member abstained.**

**Approve: 12**

**Abstain: 1**

**ii. White House Policy on DURC and PEPP**

**The BSO informed the committee that new policies have not been released.**

**iii. Reviewer timelines and expectations.**

**The Chair asked members if they felt they were able to meet timelines for review and if any members felt this should be adjusted. Members were satisfied with the current timelines and procedures. No changes were made.**

**c. Incidents requiring reporting to NIH**

**The BSO informed the committee that no incidents were reported to the IBC Office.**

**d. IBC Member Training**

**The BSO shared that Dr. Castro from the Center for Biotechnology & Genomics is to give presentation on current technologies in molecular methods this fall; the date is TBD but will occur after new members are on-boarded in the fall.**

**3. Public Comments**

**No members of the public were present at this meeting.**

**4. Closure of NIH-related business**

**The Chair asked if members had any additional NIH-related matters to discuss. Hearing none and having met the end of the agenda, the Chair adjourned the meeting at 123**

## PROTOCOL SUMMARY

**VOTE: Approve: 13; Abstain: 0; Opposed: 0**

*NOTE: Applications presented for approval have been electronically reviewed prior to the meeting. All previously requested clarifications and deficiencies, including training deficiencies, have been corrected or completed prior to the meeting. A full committee review was not requested by any member during the electronic review process. The final application is presented for review in the meeting prior to the vote. The application template can be reviewed online in the IBC homepage: <https://www.depts.ttu.edu/ehs/academicsafety/icc/ibc.php>*

Principal Investigator	Yim, Sun Hee
Protocol Number	IBC-2025-1193
Protocol Title	Environmental impact on aging.
Type	New
Highest Risk Group & Containment Level	RG2, BSL2
NIH Guidelines Section(s)	Section III-D-1-a, Section III-F-8
Work Requirements: <ul style="list-style-type: none"><li>• Training</li><li>• OHP Enrollment</li><li>• Other Considerations</li></ul>	Autoclave Training, Biosafety Training, Bloodborne Pathogen Training, rDNA training, lab-specific training pertinent to cell culture work will include sharps training, disinfectant preparation and use, spill response, and use of alcohol burner and carcinogens such as EtBr OHP enrollment offered for use of human materials.
Risk Management Highlights	Engineering controls: Unducted A2-BSC, safety cups & sealed rotors during centrifugation, fume hood PPE: standard PPE, double gloves in BSC, enhancements for use of liquid nitrogen, cryoprotection and autoclaves
Project Lay Summary	Environmental factors, such as pollutants, particles, and chemicals, influence the ecosystems and human health. We plan to investigate how human activity driven factors, such as pollution, perfluoroalkyl and polyfluoroalkyl substances (PFAS), and other environmental contaminants, contribute to the development of aging and age-related diseases. Our research focuses on utilizing molecular biology tools in combination with systems biology approaches, including the integration

and analysis of multi-omics data, to uncover the underlying mechanisms and identify potential biomarkers or therapeutic targets. Our research program utilizes a range of biological models, including Escherichia coli DH5a (BSL-1), mammalian cell culture systems conducted at BSL-1 and BSL-2 levels, depending on the specific cell lines and procedures involved. Importantly, our research does not involve the intentional use of biological or chemical toxins, or any materials classified as hazardous under current safety regulations.

Transfection of human cell lines with rDNA constructs containing fluorescent tags using standard techniques will be conducted to aid in visualization of cells during training of personnel in preparation of handling the cells for the experimental step. Cells will then be exposed to the environmental pollutants PFAS and microplastics, and cell viability assays, imaging, and protein/RNA extraction will follow to assess molecular and phenotypic outcomes.

Comments from electronic review.

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NIH Guidelines	1	1) Please describe your animal work requiring BSL2 containment on the animal work page. 2) Please make selections for your addgene vectors.	Modified. Our current IACUC protocol covers only wild-type animals obtained from Jackson Laboratory, which are classified under BSL-1.
Methodology	1	1) Please add details to the Methodology section; the information provided is insufficient. There is no information for the rDNA work, the human/animal cell culture work, or downstream work with the animal tissues.	Answer to Q1: modified. I would like to clarify that the recombinant DNA (rDNA) used in our laboratory is solely for undergraduate training purposes. Specifically, we use one of the safest and most commonly studied forms of rDNA?such as plasmids encoding Green Fluorescent Protein (GFP)?which are widely used in high school and undergraduate teaching laboratories due to their well-established safety profile and lack of associated health risks. These activities are designed to provide hands-on educational experience for students in basic molecular biology techniques, without involving any hazardous or pathogenic materials. However, if this level of regulatory scrutiny continues to apply to such routine and low-risk training exercises, I may need to reconsider or potentially discontinue this component

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			of the undergraduate research (UGR) program. I am, of course, happy to work with your office to clarify any remaining concerns and ensure compliance, but I wanted to express the impact this may have on student training opportunities.
Transport and Shipping	1	1) For the shipping question, Please include the details of how you will prepare the shipments and reference the SOP number or specify the SOP to which you are referring.	
Human/ Non-Human Primate Materials	1	<p>Just so you are aware, you must list all cell lines. Orders for cell lines not listed will not be approved.</p> <p>1) Please provide the ATCC catalogue number in the "Provide more details about the selections above" section.</p> <p>2) Please correct the information in the "Briefly describe the materials including if the materials have undergone testing and/or purification measures, known contaminants (Epstein-barr virus), etc." section. HeLa and HEK cells both have contaminants that need to be listed.</p> <p>2) In the "Exposure: Describe the following." section, please add what will happen if personnel are exposed to the cells and an appropriate mitigation measures if such an exposure occurs (i.e., if they spill it on their hands, they need to wash with soap and water). We advise you to either removed the following or reference sources for the claim, "no adverse health outcomes from exposure to these cell lines have been reported." As written, this implies known exposure and sufficient follow up. Just</p>	<p>Answer to Q2: We routinely use various mammalian cell lines obtained from the American Type Culture Collection (ATCC), including HeLa and HEK293 cells. These cell lines are provided by ATCC with certification of authentication and screening for contamination, including mycoplasma. HeLa cells are known to harbor integrated human papillomavirus (HPV-18) sequences, and HEK293 cells are known to contain adenoviral sequences due to their derivation. These characteristics are well-documented and do not pose additional biosafety risks under standard BSL-2 practices. All cell lines have undergone thorough testing and quality control by ATCC prior to distribution. In our laboratory, we follow institutional biosafety protocols and aseptic techniques to minimize any risk of contamination or exposure. We have not encountered contamination issues to date, and cell lines are regularly monitored during use. Answer to Q3 (or Q2): These cell lines are non-infectious and replication-incompetent in humans. HeLa, HEK293, and MCF-7 are</p>

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		because there either hasn't been a significant enough exposure to cause disease or be linked to adverse outcomes, does not mean that one could not occur with a sufficient exposure incident.	immortalized cell lines and are handled under BSL-2 conditions primarily due to their origin (e.g., tumorigenic or virally transformed), not because they pose direct infectious risks. They are not capable of causing infection or disease in healthy individuals under normal laboratory conditions. Biosafety guidelines (e.g., from CDC, NIH, WHO) recommend BSL-2 practices for these lines, reflecting standard precaution rather than evidence of harm. These guidelines do not cite any documented cases of laboratory-acquired illness or adverse health effects specifically from exposure to these cell lines. Longstanding use in labs worldwide. HeLa has been used since the 1950s, HEK293 since the 1970s, and MCF-7 since the 1970s-80s. Despite millions of experiments and wide global use, there are no published reports of health issues attributed to routine handling of these cell lines.
Human/ Non-Human Primate Materials	1	To eliminate confusion, please move discussion of commercial cell lines to a new entry .  You have not listed any commercially available cell lines.	Modified.
Facilities & Locations		Please add a line for 117A	Drop down does not allow me to add 117A.
IBC Personnel	1	1) Please attach the "Personnel Assurances" form for yourself. Link (must be downloaded and opened in adobe): <a href="https://www.depts.ttu.edu/ehs/forms/Cayuse_IBC/PERSONNEL_ASSURANCES_2023_RC.pdf">https://www.depts.ttu.edu/ehs/forms/Cayuse_IBC/PERSONNEL_ASSURANCES_2023_RC.pdf</a> 3) Please select your activities. 4) Please provide your information on the Qualifications	



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IBC Personnel	1	<p>1) Will any other faculty, graduate students, undergraduate students also perform any work on this protocol this work? If yes, they will need to be added here as well by completing the registration form: <a href="https://www.depts.ttu.edu/ehs/academicsafety/Biosafety/ibccayuse-personnel.php">https://www.depts.ttu.edu/ehs/academicsafety/Biosafety/ibccayuse-personnel.php</a></p> <p>2) Please attach the "Personnel Assurances" form for yourself.</p> <p>Link (must be downloaded and opened in adobe): <a href="https://www.depts.ttu.edu/ehs/forms/Cayuse_IBC/PERSONNEL_ASSURANCES_2023_RC.pdf">https://www.depts.ttu.edu/ehs/forms/Cayuse_IBC/PERSONNEL_ASSURANCES_2023_RC.pdf</a></p>	<p>There will be a graduate student, who is part of the research team; however, he will not be involved in any chemical or biological work. His role is exclusively focused on data science and computational analysis. Additionally, I currently have four undergraduate researchers (UGRs) working in the lab. Their activities are limited to BSL-1 level procedures or lower, and they will not be handling any hazardous materials or conducting work that falls under higher biosafety levels. I was unable to locate a drop-down menu option to appropriately categorize these specific roles. Please advise on how best to reflect these responsibilities within the system, or let me know if further clarification is needed.</p> <p>Q2: I tried to open the file in various way, but unable to open it.</p>
Protocol Overview	1	<p>1) Please provide some additional details in the Summary. Frequently, itemized objectives for the work are added and may be useful here.</p> <p>2) Just so I understand this correctly, you are investigating 1) how human activities produce the environmental factors and 2) the impact of these factors.</p>	
Vectors/ Plasmids	1	<p>1) Please clarify if this is gene drive or not as gene drive was not selected in the NIH guidelines section (D8). Gene drive is defined as a technology whereby a particular heritable element biases inheritance in its favor, resulting in the heritable element becoming more</p>	<p>Modified. The Green Fluorescent Protein (GFP) is derived from the jellyfish <i>Aequorea victoria</i>, a non-pathogenic marine organism. GFP is a well-characterized reporter protein that fluoresces when exposed to specific wavelengths of light and has no</p>

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		<p>prevalent than predicted by Mendelian laws of inheritance in a population over successive generations.</p> <p>2) Please provide a list for each plasmid of the inserts or targets along with the intended result in the "List the following for all nucleic acid inserts or targets:" section. I have added numbers to the plasmids and to this section to help with this.</p> <p>3) For each of the inserts or target genes, please describe what the function or effect is in the "When a foreign gene is expressed, provide the following information:" section. Currently marker proteins such as GFP are listed. We will need a comprehensive list of the target genes.</p>	<p>known toxic or pathogenic effects in humans or animals. As such, its use does not meet the criteria outlined in NIH Guidelines Section III-D-8, and this section is not applicable. Fluorescent Proteins (i.e., GFP) is widely recognized as a safe and non-toxic reporter protein. Due to its well-documented safety profile and ease of use, fluorescent proteins are commonly used in high school and undergraduate science education, particularly in biotechnology and genetics courses. It serves as an ideal teaching tool, enabling students to visualize biological processes such as bacterial transformation and protein expression in real-time.</p>
In vivo work	1	<p>1) We will need all sections here completed before we could approve this. It sounds like this may be work that is planned for the future but does not yet have a plan. It may be best to remove the animal work at this time and focus on the cell lines and genomics work.</p> <p>2)"Biohazardous agent administration details: An amendment will be made once the research direction related to the specific agents and their usage is finalized and approved." To be clear here, the amendment would need to be made and approved by the IBC prior to your IACUC approval. You indicated using whole animals that will require ABSL2. Please describe this work or remove that selection from the nucleic acids page.</p> <p>3) Please indicate how your how your breeding is EXEMPT from the NIH guidelines. Your IACUC protocol is specifically for breeding animals only. You state, "Methodology to create or breed transgenic animals : will be addressed in IACUC protocol." This response is</p>	Modified in the text.

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		<p>insufficient for regulatory compliance. The IBC has purview over the creation and generation of transgenic animals through the NIH Guidelines; for example, if the breeding results in the creation of gene drive modified rodents (Section III-D-8), ABSL2 is required, and IBC approval is needed for the work.</p> <p>However, certain breeding experiments are exempt under Appendix C-VIII of the <i>NIH Guidelines</i>. This exemption covers the breeding of two different lines of transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new line of transgenic rodent that can be housed at BL1 if:</p> <ol style="list-style-type: none"> <li>1. both parental rodents can be housed under BL1 containment; and</li> <li>2. neither parental transgenic rodent contains the following genetic modifications: <ul style="list-style-type: none"> <li>○ incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or</li> <li>○ incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and</li> </ul> </li> <li>3. the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.</li> </ol>	
Risk Management	1	<p>1) I did not see any safety cones in your laboratory. Are you certain they will be used?</p> <p>2) Please select sealed rotor, sealed tubes, and sharps container in the engineering controls.</p> <p>3) Please respond to the "Are sharps recapped in the laboratory?" question.</p>	<p>Answer to Q1: I believe we have an adaptor for the centrifuge cone</p> <p>Answer to Q8: We regularly use ethanol (EtOH), Lysol, and Clorox in the lab and will apply them properly as needed for disinfection. In the event of a spill or incident, lab members are responsible for cleaning the affected area promptly</p>

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		<p>4) Please clarify which time will be used for what type of materials in the autoclave settings. Texas state law requires biological waste to have a 30 minute hold time at 121 C at 15 psi, so the 15 minute cycle cannot be used for waste.</p> <p>5) Please list other chemical disinfectants (i.e., 70%EtOH, accelerated hydrogen peroxide).</p> <p>6) The materials you are disinfecting do have a high organic content (You indicated having serums, and there is also liquid cell culture). Please correct this check box.</p> <p>7) Please complete the "Will mixed waste(s) be generated?" section. Mixed wastes are biological waste mixed with chemical wastes or radioactive wastes. Please specify whether these will be generated.</p> <p>8) Please specify what disinfectant you are using for the routine cleaning and what is being used for floors in the "How will routine cleaning of the lab space and equipment be performed? How often?" section. Please elaborate on what you mean by "lab-wide" cleaning and why biannually is your proposed frequency.</p> <p>9) If double gloving is only for specific operations, please select the Gloves, Nitrile and/or Gloves, latex options as well. You should also indicate procedures for which double gloving is required.</p> <p>10) Biobarrels were not present in your laboratory, nor are they appropriate for liquid waste disposal. Please clarify what methods are used for the liquid waste and solid waste in the corresponding sections. Currently there is solid waste procedures in the liquid waste procedures.</p> <p>11) Please complete the section "Describe normal laboratory operations. Insert your procedures for the following:" section. Currently the definitions of the items are listed - we know what these things are. Please</p>	<p>and safely. However, I would like clarification on whether this question is referring to routine floor cleaning by faculty and students. If so, I am a bit surprised, as general facility maintenance (including floors) is typically handled by custodial staff, not research personnel. Regarding equipment cleaning, we only use 70% ethanol to wipe down surfaces, as other cleaning agents may damage sensitive metal components of laboratory instruments. By "lab-wide cleaning," I am referring to a more comprehensive effort beyond routine daily cleaning. This includes dusting off and wiping down unattended instruments, cleaning shelving units where chemicals and supplies are stored, organizing stock rooms, and addressing areas that may accumulate dust or clutter over time but are not part of the regular cleaning schedule. The proposed biannual frequency is based on the fact that our lab space is well-maintained on a day-to-day basis, and most surfaces and equipment are already cleaned regularly by lab members as needed. A full lab-wide cleaning twice a year ensures deeper maintenance without significantly disrupting ongoing research activities. Answer to Q9: We have purchased various types of gloves. They will be used properly. Answer to Q10: Can I have a biobarrels? Should I buy one? Answer to Q11: I have listed detail in WASP. Should I repeat here? Answer to Q12: All students are required to receive proper instruction before using an ethanol lamp in the laboratory. Although many have previous experience (some dating back to junior high or high school), formal lab-specific training is provided to ensure safety and consistency. Answer to Q13: We study aging, and there is no preventive medicine for this. Due to potential exposure to animal dander, dust, or</p>

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		<p>insert the procedures of how your lab will be operating.</p> <p>11a) Please elaborate on the "Describe emergency procedures. Insert your procedures for the following:" section.</p> <p>11b) Please indicate for #1 the steps for your spill cleanup and indicate what disinfectant will be used along with its contact time. Most laboratory spills will not require emergency response.</p> <p>11c) Please indicate if washing the area with soap and water will be done for #2.</p> <p>11d) Please describe the steps of your lab's emergency response plan in #3.</p> <p>12) Please indicate how risks are communicated to lab personnel. Describe the lab-specific training and proficiency evaluation you provide your personnel. Indicate recurrence of training and proficiency evaluation.</p> <p>13) You indicated that there are prophylactics available for your agents. Please provide the information for recommended prophylactics in the "additional details" section available at the bottom of the page.</p>	<p>other biological agents during routine research activities, any lab members involved in animal work will be required to receive Tetanus/Diphtheria (Td) vaccination in accordance with institutional biosafety and occupational health guidelines.</p>
Methodology	2	<p>1) Please provide the details on what methods will be used for the rDNA work. It does not need to be step by step for each process done, but it should describe the overview of your process and what is being done with the materials.</p> <p>Office note: As an example, you may start with "Plasmids that code for fluorescent proteins will be amplified in E. coli DH5a using standard methods as undergraduate training. The fluorescing cells will then be observed for successful transformation. These activities are designed to provide hands-on educational experience for students in basic molecular biology</p>	<p>Response to Q1: We are using the guidelines established by the UC Berkeley undergraduate training program, QB3 Lab Fundamentals Bootcamp (<a href="https://qb3.berkeley.edu/education/lab-fundamentals-bootcamp/">https://qb3.berkeley.edu/education/lab-fundamentals-bootcamp/</a>). If TTU undergraduate students are interested in learning more during the summer, I would like to expand our training program based on this model. The QB3 Lab Fundamentals Bootcamp is designed for undergraduates participating in summer research projects at UC Berkeley, particularly those with little or no prior research experience. Response to Q2: Our current</p>

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		<p>techniques." It is possible the committee may ask for more details during review, but I think a statement like that will be a great start. Feel free to copy, paste, and alter as needed to fit the work.</p> <p>2) If the transgenic animal breeding needs to be added to the protocol, it should be described here also.</p> <p>3) You state "Transient or stable transfection of cell lines with rDNA constructs will be conducted to study redox biology and protein expression dynamics. Cell viability assays, imaging, and protein/RNA extraction will follow post-transfection to assess molecular and phenotypic outcomes.". This indicates that the human cell lines will be genetically modified as well. If so those modifications will need to be explained on the 'Vectors/Plasmids' page. Will the human materials also be modified?</p> <p>4) Is the undergraduate training associated with a course? Could you attach a syllabus if it is?</p>	<p>IACUC protocol does not describe the transgenic animals, thus once the specific animal models are needed to be investigated, I will submit an amendment. Response to Q3: Detailed method are listed in the Q1. Human cell line will NOT be genetically modified in our research or UG training. The vectors does not integrated to the genome, thus modification will not occur. Response to Q4: This is an independent study and does not require a specific syllabus.</p>
Transport and Shipping	2	<p>1) Please describe the procedure that will be used to transport the animals from the animal facility to room 117 in the "Insert your procedure(s) for the above indicated transport condition(s) including locations." section.</p>	<p>We will follow SOP Number: 030. In particular, Movement of animals within a TTU building 1. Investigators may transport animals to their approved laboratory as described in their approved protocol using direct, non-public routes. 2. Transportation must be done in appropriate enclosures according to species. 3. During transportation, animals should not be visible to the public. This may be done by placing a towel, drape, etc., over the cage, or by placing the animal(s) in nontransparent cages with adequate ventilation. 4. Empty cages should not be placed in the hallways outside of laboratories. All empty cages should be covered and returned to the animal facility. 5. Rodents may not be overcrowded for transport. Up to 2 standard rodent cages may be carried by hand.</p>

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			If 3 or more cages are to be transported, a cart is required. In all cases, cage lids must be secured to the cages with a clip, tie, or residue-free tape to prevent escape. Cages containing animals must not be stacked. 6. The water bottle should be turned upside down to prevent water dripping into the cage during transport.
Human/ Non-Human Primate Materials	2	<p>1) For clarification, will any other cells be used other than NIH3T3 and RAW 264.7?</p> <p>2) In the "Exposure: Describe the following." section, please add what will be done in the event of exposure. Regardless of the hazard, it would still be expected that personnel wash the exposed area with soap and water.</p>	<p>Response to Q1: No plan to use cells other than listed. If any other cell types are needed to culture, I will submit an amendment.</p> <p>Response to Q2: The exposure incident is likely to occur along with cell culture media containing PBS and/or BSA. Therefore, any personnel should wash the exposed area with soap and water.</p>
Human/ Non-Human Primate Materials	2	<p>1) For clarification, will any other human cells be used other than HeLa, HEK293, and MCF-7? In the reply you mentioned various cells including. We need a list of all cells that are planned.</p> <p>2) In the "Exposure: Describe the following." section, please add what will be done in the event of exposure. Regardless of the hazard, it would still be expected that personnel wash the exposed area with soap and water.</p>	<p>Response to Q1: There is no plan to utilize other cell types. If needed in the future, I will submit an amendment.</p> <p>Response to Q2: I have never heard of, nor learned from publications or guidelines, that exposure to such cell lines has caused symptoms. However, exposure is likely to occur along with cell culture media containing PBS and/or BSA. Therefore, any personnel should wash the exposed area with soap and water.</p>
IBC Personnel	2	<p>1) I marked Dr. Yim's select activities for all activities. Please ensure that is accurate.</p> <p>2) The students will need to complete the trainings since the work will be going on in a research laboratory. They can request the training here:  <a href="https://www.depts.ttu.edu/ehs/Training/index.php">https://www.depts.ttu.edu/ehs/Training/index.php</a></p>	<p>Response to Q1; YES</p> <p>Response to Q2: All student training records have been submitted. If any additional training is required, please assign it accordingly. I will ensure that each student follows the training guidelines.</p>

Page	Revision	Merged Notes	Rebuttal Info
Vectors/ Plasmids	2	<p>1) Where you list the target genes in the "List the following for all nucleic acid inserts or targets" section, it doesn't seem that the gene target name is provided, just the plasmid name and the wavelengths. Can you provide the exact name of the genes you are targeting for use?</p> <p>2) To clarify, are you inserting any genes into these plasmids or utilizing them as purchased?</p> <p>3) To clarify, are DH5a cells the only cells that will be exposed to these plasmids? They will not be used to transform any other cells types?</p>	<p>Respond to Q1: This is a self-standing vector and will not be used to combination with others or targeting other gene.</p> <p>Respond to Q2: Students are using as purchased.</p> <p>Respond to Q3: Within next year- we may transform this to the Hela cells, but nothing has been determined.</p>
In vivo	2	<p>1) Currently the breeding of BSL1 transgenic mice is approved on your IACUC protocol. Please answer the below questions with a 'yes' or 'no'. If you are unsure, please reach out to Jackson labs to ask about your breeding scheme.</p> <ol style="list-style-type: none"> <li>both parental rodents can be housed under BL1 containment; and</li> <li>neither parental transgenic rodent contains the following genetic modifications: <ul style="list-style-type: none"> <li>incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or</li> <li>incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and</li> </ul> </li> <li>the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.</li> </ol>	<p>Response to Q1: Yes</p> <p>Response to Q2: NO. Currently none is applied to our protocol.</p> <p>Response to Q3: Not applicable to our animal study.</p>



Page	Revision	Merged Notes	Rebuttal Info
In vivo	2	<p>1) Please confirm that the species is <i>Mus musculus</i> as this was added.</p> <p>2) Please indicate the total expected number of mice to be used.</p> <p>3) Please indicate what transport will be done, if any.</p> <p>4) Please complete number 1, 2, 4, 5, 7, and 8 in the "Describe the following as they apply to your work:" section.</p> <p>5) Please update #3 of the "Describe the following as they apply to your work:" section, Usage cannot be approved by the IBC unless it is described here.</p> <p>6) I moved the information from the old page here and tried to fill out the relevant sections. Please ensure everything is still accurate.</p>	<p>Response to Q1: They are all <i>Mus musculus</i>.</p> <p>Response to Q2: We have currently only have an animal breeding protocol which covers 300 animals</p> <p>Response to Q3: In the future, the mouse will be transported from the ESB2 animal facility to the PI's lab (ESBII, 117) for euthanization and tissue collection only</p>
Risk Management	2	<p>1) I added information to several sections as taken from the WASP you emailed, from other areas on the protocol, or from your comments in rebuttal. Please review this page and ensure all information is correct. I added changes or information to the other disinfectants, the routine cleaning, the solid waste treatment, normal laboratory operations, and emergency procedures. These changes do not address the below comments, which will still need your attention.</p> <p>2) You indicate that sharps will be recapped. Please review if that is correct. You will need to justify why recapping is needed and provide your recapping SOP if recapping is done. SOP 4.1 does not address recapping.</p> <p>3) Please complete #1, 2, and 3 in the "List other products used for disinfection" for each listed product (ethanol, Lysol, and clorox).</p> <p>4) In the "How will routine cleaning of the lab space and equipment be performed? How often?" section, please</p>	

Page	Revision	Merged Notes	Rebuttal Info
		<p>specify what is cleaned daily and using what disinfectant.</p> <p>Office note: The committee will be looking for how the lab surfaces (such as tables, counters, and other working surfaces), equipment, and floors will be cleaned. An SOP is not needed, but a statement about what is used on each of these things, and the contact time used will be needed.</p> <p>5) Biobarrels cannot be used for liquid waste. Please provide the methods for managing liquid waste (such as autoclaving or using bleach) in the "Insert your procedure(s) for disposing of biologically contaminated liquid waste with materials." section.</p> <p>Office note: Typically, we see that people will either autoclave or bleach their liquid waste. I would suggest choosing autoclaving since it is the best method, and using bleach as a backup for if autoclaves are not available.</p> <p>In order to request a biobarrel, if you wish to use one, you will have to contact Environmental Protection (<a href="mailto:ehs.environmental.safety@ttu.edu">ehs.environmental.safety@ttu.edu</a>) to request this service. Typically, biobarrels are not used in buildings with autoclaves present unless the waste needs to be incinerated. They will likely ask for a justification given the number of autoclaves in ESB2.</p>	
Methodology	3	<p>1) Please clarify which parts of the UC Berkeley program are being used (are they following part 1 and part 2 on the manual overview, or performing more steps indicated by projects in the sidebar). There are a number of experiments listed.</p> <p>2) The manual specifies the use of pET28b-GFP. Are your student's substituting the plasmids listed on the protocol for the pET28b-GFP?</p>	<p>Response to Q1: Revised in the text. Response to Q2: The pET vectors are designed for protein expression in E. coli, whereas our vector system (such as tdTomato-N1) is intended for expression in mammalian cells and is commonly used as a fluorescent marker. While both are widely used vector systems, their purposes differ: pET vectors are optimized for producing large quantities of</p>

Page	Revision	Merged Notes	Rebuttal Info
		Office note: based on our discussion today, you may just want to add where your plasmids, target proteins, or organisms used differ from the Berkeley manual.	proteins, which is useful for characterizing protein function or studying enzyme activity. In contrast, our system focuses on visualization rather than high-level protein production. We are currently in the early stages of training and are utilizing the curriculum from the Berkeley QB3 program. I will provide an update once we progress to the next protocol, as it depends on the availability of resources, safety regulations, and student learning readiness. Any updates will be reflected in the lab protocol accordingly. At this stage, we have only modified the protocols that are currently in use, as it is difficult to predict which resources will be available for the upcoming steps. Additionally, while the Berkeley protocol on 'Protein expression in E. coli' refers generally to 'E. coli', we have specified the use of the DH5a strain in our version. In particular, DH5a is a K-12 strain. K-12 derivative strains exempted from the requirements of the NIH Guidelines <a href="https://blink.ucsd.edu/safety/research-lab/biosafety/nih/e-coli.html">https://blink.ucsd.edu/safety/research-lab/biosafety/nih/e-coli.html</a> . (References, PMCID: PMC92342 PMID: 11010916).
Risk Management	3	<p>1 of 2) In the "How will routine cleaning of the lab space and equipment be performed? How often?" section, please specify what is cleaned daily and using what disinfectant.</p> <p>Office note: The committee will be looking for how the lab surfaces (such as tables, counters, and other working surfaces), equipment, and floors will be cleaned. An SOP is not needed, but a statement about what is used on each of these things, and the contact time used will be needed.</p> <p>2 of 2) Biobarrels cannot be used for liquid waste. Please provide the methods for managing liquid waste</p>	<p>Response to Q1 of 2): modified in the text; Each student is responsible for the area and equipment they use (such as the balance) as well as their designated bench space. This should be maintained daily whenever any lab activity is performed.</p> <p>Response to Q2 of 2): Any liquid containing biological material will be autoclaved. However, I am a bit uncertain about how to handle liquid waste that does not contain biological materials, such as buffers used for agarose gels or SDS solutions. I will reach out to EHS to clarify and ensure we are meeting TTU's specific requirements for proper disposal.</p>

Page	Revision	Merged Notes	Rebuttal Info
		<p>(such as autoclaving or using bleach) in the "Insert your procedure(s) for disposing of biologically contaminated liquid waste with materials." section.</p> <p>Office note: Typically, we see that people will either autoclave or bleach their liquid waste. I would suggest choosing autoclaving since it is the best method, and using bleach as a backup for if autoclaves are not available.</p>	
NIH Guidelines	4	<p>1 of 1) In reviewing your IACUC protocol, none of your currently approved breeds are transgenic. Please uncheck box E3 or describe the transgenic lines to be used. In unchecking this box, you would need to amend your protocol if transgenic lines are used in future work.</p>	<p>Answer to Q1.1: As indicated in our earlier response, such procedures are generally required for most animal studies; therefore, we believe it is appropriate to retain the current selection. We are in the process of preparing an animal protocol that includes the use of transgenic animals. This is a necessary step, as the NIH grants supporting this research ultimately propose the use of transgenic models. The transgenic mouse models (The Model Organism Development and Evaluation for Late-onset Alzheimer's Disease (MODEL-AD) Consortium we anticipate using are currently under development, and we expect to receive some of the available lines once they are fully characterized (<a href="https://www.model-ad.org/data-and-resources/">https://www.model-ad.org/data-and-resources/</a>). Since this is part of a multi-center consortium, it is likely that individual PIs will have access to new lines as they become available. In addition, my NIH R15 grant specifically proposes studies involving Peroxiredoxin IV knockout (KO) mice. I plan to submit amendments to our animal protocol to include these new lines in the near future.</p>

Page	Revision	Merged Notes	Rebuttal Info
Methodology	4	<p>1 of 3) In your description of Human/Animal Cell Culture Work, you state, "Transient or stable transfection of cell lines with rDNA constructs will be conducted to study redox biology and protein expression dynamics." This work is not described on the <i>Vectors/Plasmids</i> page and must be added for review.</p> <p>2 of 3) Please clarify here how the DH5a will be used in the undergraduate teaching. It does not appear that the DH5a can express the fluorescent proteins encoded by the plasmids presented in this protocol; it can only amplify as you indicated on the <i>Vectors/Plasmids</i> page. As noted in your reply, "...our vector system (such as tdTomato-N1) is intended for expression in mammalian cells...", thus, it is unclear how these will be used.</p> <p>3 of 3) Please indicate the experiments where your materials will differ from the UC Berkeley Bootcamp. For example, you indicated your mammalian vectors are to be used with the students. Please indicate which elements of the program will use these materials.</p>	<p>Response to Q1: We anticipate expressing fluorescent protein vectors, most of which are regulated by redox-responsive systems, such as cysteine-cysteine (Cys-Cys) disulfide bonds that assist in proper protein folding required for fluorescence activation. These vectors are commonly used to study protein expression dynamics—for example, in FRET (Förster Resonance Energy Transfer) systems—where fluorescence serves as a real-time indicator of protein expression and folding states.</p> <p>Response to Q2: E. coli DH5a will be used solely for plasmid amplification. After amplification, the protein expression vectors will be transfected into mammalian cells to achieve proper expression of fluorescent proteins. These cells will then be visualized to confirm successful expression and determine the subcellular localization of the fluorescent proteins.</p> <p>Response to Q3: The UC Berkeley protocol that inspired this course module is designed to teach protein expression, rather than visualization. However, due to our limited access to protein purification equipment, we have adapted the protocol to use fluorescently tagged expression vectors, allowing visualization as a substitute for purification. The procedure includes preparing bacterial culture media, growing colonies on plates and in liquid culture, and plasmid isolation—adapted from the UCB protocol. Implementation of the full protocol will depend on available resources, student progress, and the timeline for approval of related safety protocols.</p>

Page	Revision	Merged Notes	Rebuttal Info
Human/ Non-Human Primate Materials	4	1 of 1) In the <i>Briefly describe the materials</i> space, please remove the statement, "We do not anticipate any contamination or viral infections." Please add that RAW 264.7 was transformed with Abelson murine leukemia virus and requires BSL2 containment.	Response to Q1: Although the RAW cell line is classified as BSL-2, the associated Abelson murine leukemia virus (A-MuLV) does not pose a known infectious risk to humans. A-MuLV is a retrovirus capable of transforming murine cells, but it is not associated with human disease. Its oncogenic component, the abl gene, has a human counterpart; however, in humans, this gene is part of normal cellular DNA and not of viral origin. When implicated in diseases such as chronic myelogenous leukemia (CML) or certain lymphocytic leukemias, abl-related abnormalities arise from chromosomal translocations not from viral infection.
Human/ Non-Human Primate Materials	4	1 of 2) Please remove the statement "All of these cell lines are tested and confirmed to be free of known contaminants, so we do not anticipate any contamination matter. "  2 of 2) Please change "routine laboratory exposure" to "routine laboratory use". Exposures to human materials in the laboratory should not be routine, especially when "appropriate biosafety conditions" are used.	Response to Q1; done Response to Q2: done.
Options	4	1 of 1) Presently, your animal work will not involve the exposure of animals to an infectious agent, other biological materials and/or creation, breeding, or use of transgenic animals. Please uncheck this box. If you choose to maintain this box, you will need to fully describe your intended use of animals for the above listed purposes.	Response to the Q1.1; Thank you for your input. Our current animal protocol does not include the specific procedures you mentioned. However, such elements are generally inherent to most animal studies, and we anticipate submitting an amendment to our protocol in the near future to address this. In practice, if an animal protocol excludes these types of investigations entirely, it would significantly limit the scope of meaningful research. Therefore, I believe it is appropriate to check 'Yes' in response to the question: 'Check this box if work with whole

Page	Revision	Merged Notes	Rebuttal Info
			animals will involve the exposure of animals to an infectious agent, other biological materials, and/or the creation, breeding, or use of transgenic animals.
Vectors/ Plasmids	4	<p>1 of 3) You only indicate amplification in DH5a. Please indicate what cell line will be used to express the fluorescent tags in these mammalian expression vectors.</p> <p>2 of 3) If your plan is to express these mammalian expression vectors in DH5a, please describe the mechanism by which DH5a express the fluorescent proteins for visualization.</p> <p>3 of 3) Please correct plasmid 10's catalog number. It should be 54605.</p>	<p>Answer to Q1: We will use one of the available BSL-1 cell lines, such as A549, HCT116, HepG2, or MCF7. These vectors were purchased solely for undergraduate training purposes, and their use will depend on UGR (Undergraduate Research) course enrollment and progress. If any of the above cell lines are used, an amendment will be submitted accordingly.</p> <p>Answer to Q2: The protein is not expressed in E. coli DH5a. This bacterial strain is used only for plasmid amplification.</p> <p>Answer to Q3: Done. Thank you.</p>
In vivo work	4	1 of 1) In consult with IACUC, your currently approved breeding scheme does not use transgenic rodents. Crossbreeding the currently approved strains will therefore not result in generation of additional transgenic rodents. It is recommended this all animal work be removed. If you wish to maintain animal work on this application, you will need to describe it in full so that an appropriate review can be conducted.	Answer to Q1: As described in the section above, we are preparing to submit an IACUC amendment that will include the acquisition and use of transgenic mouse models. While specific details are still being finalized, we anticipate submitting the amendment within the next few months. Accordingly, it is more fitting to retain this section in the current version of the document.

**VOTE:**

- ☐ A motion was made to table the application pending additional information from the PI:
- ☐ A motion was made to defer the application back through the DMR process.
- ☒ A motion was made to approve the registration as is.
- ☐ A motion was made to approve the registration pending the following changes or conditions to be met:

## PROTOCOL SUMMARY

**VOTE: Approve: 13; Abstain: 0; Opposed: 0**

*NOTE: Applications presented for approval have been electronically reviewed prior to the meeting. All previously requested clarifications and deficiencies, including training deficiencies, have been corrected or completed prior to the meeting. A full committee review was not requested by any member during the electronic review process. The final application is presented for review in the meeting prior to the vote. The application template can be reviewed online in the IBC homepage: <https://www.depts.ttu.edu/ehs/academicsafety/icc/ibc.php>*

Principal Investigator	Gollahon, Lauren S
Protocol Number	IBC-2024-1166
Protocol Title	The Role of [REDACTED] in Mitigating Leaky Gut in Bovine
Type	New
Highest Risk Group & Containment Level	RG2, BSL2
NIH Guidelines Section(s)	Section III-F-8
Work Requirements: <ul style="list-style-type: none"><li>• Training</li><li>• OHP Enrollment</li><li>• Other Considerations</li></ul>	Autoclave Training, Biosafety Training, Bloodborne Pathogen Training, rDNA training, lab-specific training pertinent to cell culture work, disinfectant preparation and use, BSC use, and spill response.
Risk Management Highlights	Engineering controls: Unducted A2-BSC, safety cups & sealed rotors during centrifugation PPE: standard PPE, double gloves in BSC, enhancements for use of liquid nitrogen, cryoprotection and autoclaves.
Project Lay Summary	<p>This proposal addresses the issue of Liver Abscesses in cattle. This syndrome causes distress, dehydration and malnutrition as well as challenging the animal immune system. We will utilize [REDACTED] a tripartite motif-containing protein that has a role in cell membrane repair, to induce repair and regeneration of bovine liver and potentially intestinal epithelial cells in vitro.</p> <p>Objectives:</p> <p>A) Elucidate [REDACTED] Mechanism of Action: Study the protein's interactions and effects on</p>



gastrointestinal (GI) epithelial cells.

B) Evaluate [REDACTED] Protein Stability: Test expression and purification of recombinant MG53 and its stability under physiological conditions.

C) Develop [REDACTED]-Based Therapeutics: Analyze its potential application in bovine gut health.

Experimental Design

Phase 1: Gene Cloning and Validation. Use PCR to amplify the bovine [REDACTED] gene from cDNA derived from bovine muscle tissue samples. Cloning into Vectors: pEGFP-C1 vector for functional studies and cellular localization. His-tagged plasmid for recombinant protein expression and stability analysis.

Phase 2: Transfection and Functional Studies. Maintain bovine GI epithelial cell lines under optimal conditions. Introduce plasmid constructs into the cells using lipofection or electroporation methods.

Localization and Expression Analysis: Visualize GFP-tagged target protein using fluorescence microscopy. Measure expression levels via quantitative RT-PCR and Western blotting. Functional Assays: Assess epithelial barrier integrity using Transepithelial Electrical Resistance (TEER) and permeability assays.

Phase 3: Recombinant [REDACTED] Production and Stability Studies. Expression in E. coli: Transform E. coli BL21(DE3) cells with the His-tagged plasmid. Protein Purification: Use Ni-NTA affinity chromatography for purification. Stability Testing: Assess [REDACTED] stability under different pH levels, temperatures, and proteolytic conditions using SDS-PAGE.

Comments from electronic review.

Page	Revision	Merged Notes	Rebuttal Info
Human/Non-Human Primate Materials	0001	1) Please complete the "Exposure: Describe the following." section. This can be done from a universal precautions standpoint (wash exposed the area with soap and water, etc..).	
Facilities & Locations	0001	1) In the text box, please indicate the building, room, and inspection date.	

Page	Revision	Merged Notes	Rebuttal Info
IBC Personnel	0001	1) Your student "A" is missing the OHP declination form; it can be declined but an answer must be given.	Thank you we will address.
Vectors/ Plasmids	0001	1) Please also add the vendor and catalog number.	
Certification	0001	1) Please type your name here to serve as the " PI signature".	
Risk Management	0001	<p>1) Please add the frequency you will mop to the routine cleaning section.</p> <p>2) In the liquid waste section, it mentions you will use biobarrels. Liquids cannot go in biobarrels. Please clarify what type of liquids.</p> <p>3) In the "Describe emergency procedures. Insert your procedures for the following:" section, please add what disinfectant and what contact time is to be used for the spill cleanup.</p> <p>4) In the "Describe normal laboratory operations. Insert your procedures for the following:" section, please complete 1, 2, and 3.</p> <p>5) Please complete the "Principal Investigator's Assessment of Risk" section.</p> <p>6) Please answer yes or no for the "Medical Surveillance (check all that apply):" questions.</p>	Addressed

**VOTE:**

- ☐ A motion was made to table the application pending additional information from the PI:
- ☐ A motion was made to defer the application back through the DMR process.
- ☒ A motion was made to approve the registration as is.
- ☐ A motion was made to approve the registration pending the following changes or conditions to be met:

## PROTOCOL SUMMARY

**VOTE: Approve: 12; Abstain: 1; Opposed: 0**

*NOTE: Applications presented for approval have been electronically reviewed prior to the meeting. All previously requested clarifications and deficiencies, including training deficiencies, have been corrected or completed prior to the meeting. A full committee review was not requested by any member during the electronic review process. The final application is presented for review in the meeting prior to the vote. The application template can be reviewed online in the IBC homepage: <https://www.depts.ttu.edu/ehs/academicsafety/icc/ibc.php>*

Principal Investigator	Tran, Son
Protocol Number	IBC-2025-1208
Protocol Title	Development of new gene editing technology in crop plants
Type	New
Highest Risk Group & Containment Level	RG1, BSL1
NIH Guidelines Section(s)	While this work does involve gene editing in plants, NIH Guidelines do not apply the Cas protein genome modifications at this time.
Work Requirements: <ul style="list-style-type: none"><li>• Training</li><li>• OHP Enrollment</li><li>• Other Considerations</li></ul>	Autoclave Training, Biosafety Training, rDNA training, lab-specific training pertinent to plant containment and molecular methods, disinfectant preparation and use, and spill response. OHP is not required.
Risk Management Highlights	Engineering controls: Centrifuge Safety Cups, Fume hood, Sealed tubes/vials/plant PPE: Nitrile gloves, Thermal Protective gloves; Goggles and safety glasses as appropriate; reusable Lab Coat,
Project Lay Summary	We will develop a new gene editing technology using ribonucleoproteins (RNPs; synthetic Cas protein and sgRNA purchased from commercial Vendors) complex in sorghum and cotton. No transgenic whole plants will be generated because we do not insert any DNA into the plant genome. The RNP complex will be delivered into plant cells for editing the target genes. The RNP-transfected plant cells will be tested for editing efficiency by DNA sequencing. No plants will be used or stored in the lab; only in the greenhouse and growth chambers

Comments from electronic review.

Page	Revision	Merged Notes	Rebuttal Info
Methodology	0001	1) Will any plant samples be taken from the growing plants? 2) Please include more details in the methods section. This does not need to be step by step for all of your procedures, but it should include what general actions are taken to achieve the goals of the experiment.	Answered
Transport and Shipping	0001	1) 2 labs and the phytotron were listed in facilities. Will any material transport between any of the 3 locations? If so, transportation should be marked 'yes' and the details of transport included.	
Facilities & Locations	0001	1) Please ensure all added information is accurate.	
Facilities & Locations	0001	1) Please ensure all added information is accurate. 2) Please include the last date of the EHS survey. Office Note: Each room listed needs a separate entry. This was done for you. Please review for accuracy.	
Facilities & Locations	0001	1) Please ensure all added information is accurate. 2) Please include the last date of the EHS survey.	
IBC Personnel	0001	1) Please indicate who the primary contact is. 2) Some personnel are not up to date on their training, see what is needed below: <ul style="list-style-type: none"> <li>• <b>Dr. Ha</b> Autoclave Safety, rDNA, Lab Safety, and Biosafety</li> <li>• <b>Sanjida</b>: rDNA</li> </ul>	Done

Page	Revision	Merged Notes	Rebuttal Info
		<ul style="list-style-type: none"> <li>• MD Mezanur: Hazardous Shipping, Autoclave Safety, rDNA, Lab Safety, and Biosafety</li> </ul> <p>3) There are some incomplete personnel assurance forms attached. Please correct and reattach. Listed below:</p> <ul style="list-style-type: none"> <li>• Nhi Pham: PI signature missing</li> <li>• Sanjida: PI signature missing</li> <li>• MD Mezanur: start date, name, training, and PI signature missing</li> <li>• Touhidur: PI signature missing</li> </ul> <p>4) There is a personnel assurance form added for personnel not listed. Is this person still working in the lab? If so, they will need to be added to personnel.</p> <p>5) Please add a personnel assurance form for Dr. Tran.</p>	
Protocol Overview	0001	<p>1) Please clarify the scope of the work. According to comments left on requisition 200655940 in Techbuy, gene editing of plants is planned. Additionally, on the vectors and plasmids page, two plant species are listed as hosts and in the attached SOP recombinant work and gene editing of plants is indicated.</p> <p>2) Please clarify if any plants are used and stored by your lab. It is the IBC's understanding that you have a USDA permit for plants. Is this accurate?</p>	
Vectors/Plasmids	0001	<p>1) Cotton and sorghum are listed as host plants. What role will the plants serve in the research? They will need to be added to the Plants page.</p> <p>2) In the attached SOP, editing of plants is indicated. That work should be described on this protocol.</p> <p>Office Note: I have started an entry on this page for you for each.</p>	
Plants and Macroscopic Fungi	0001	<p>1) Please complete all parts on this page.</p>	
Risk Management	0001	<p>All sections should be filled on the page. The committee does not accept references to attachments alone.</p> <p>1) Please complete the "List all biosafety cabinets that will be used for the work. Address the following for..." section for all BSCs. Please note, the phytotron does not currently have a BSC, it has 2 laminar flow hoods.</p>	

Page	Revision	Merged Notes	Rebuttal Info
		<p>2) Please complete the "Autoclaving: Indicate the location(s) of the unit(s), materials treated, and the settings used." section.</p> <p>Please complete the "Bleach Solution(s)" section. Please complete the "How will routine cleaning of the lab space and equipment be performed? How often?" section. The frequency of cleaning should be added along with what is used to clean and what is used on floors.</p> <p>In the, "Insert your procedure(s) for disposing of biologically contaminated liquid waste with materials." section, EHS does not pick up liquid waste. What is currently being done with liquid waste? Is it being bleached or autoclaved?</p> <p>Please add additional details to the, "Insert your procedure(s) for disposing of biologically contaminated solid waste. Special considerations for animal, arthropod, and plant work should be addressed in their respective sections but can be copied here." section.</p> <p>Please complete #1,2, and 3 the "Describe normal laboratory operations. Insert your procedures for the following:" section.</p> <p>Please complete #1,2,3, and 4 of the "Describe emergency procedures. Insert your procedures for the following:" section.</p> <p>Please complete all sections of the "Principal Investigator's Assessment of Risk". NA is an inappropriate response to both fields.</p>	
Methodology		<p>1) Please describe the manner in which the plants are edited also. This does not need to be step by step, but rather a description of the general process.</p> <p>2) As flowers will be collected, please answer 'yes' to the question, "Will samples or specimens be collected as a part of this work?"</p>	

Page	Revision	Merged Notes	Rebuttal Info
Vectors/ Plasmids	0002	1) Please include the vendor information for the RNP complex. Office Note: The committee would consider this RNP complex a "vector" in terms of filling out the protocol. We will bring this up to the committee as it seems this term may not adequately describe the work that your group is working on. Feel free to email the IBC office if you have any questions or suggestions you want to share about this.	
Plants and Macroscopic Fungi	0002	1) Will pollen also be collected from this plant?	
Risk Management	0002	<p>1) In the "List all biosafety cabinets that will be used for the work. Address the following for each unit:" section, please only list Biosafety Cabinets (BSC). Laminar flow hoods and Centrifuge cups are not needed here.</p> <p>2) Can you clarify if the Class I Safety cabinet listed is indeed a Biosafety Cabinet? Flammables are not to be used in BSCs.</p> <p>3) Please include the certification expiration for the Class I cabinet if it is a BSC.</p> <p>4) In the "Autoclaving: Indicate the location(s) of the unit(s), materials treated, and the settings used." section, please include what materials are treated. This can be generic (ex., waste, media, lab ware).</p> <p>5) In the "Autoclaving: Indicate the location(s) of the unit(s), materials treated, and the settings used." section, please clarify the pressure used as "1 psi" may be a typo. Atmospheric pressure is 14.7 psi and autoclaves should be pressurized during use.</p> <p>6) In the "Bleach Solution(s)" section, please change the contact time to the time that the bleach is in contact with the surface.</p> <p>7) 20% bleach for mopping can produce irritating fumes, would you like to use a 5% bleach solution instead for mopping floors?</p>	



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		<p>8) In the "Describe normal laboratory operations. Insert your procedures for the following:" section, please complete #1,2, and 3. The committee will not accept references only. Please summarize the information. The details listed should be specific to your lab operations. Question 1 can be answered by listing the engineering controls you plan to use for this project and what hazards you are using them to mitigate. If you have questions about the level of detail needed feel free to reach out to the IBC office.</p> <p>9) In the "Describe emergency procedures. Insert your procedures for the following:" section, please complete #1,2,3, and 4. The committee will not accept references only. Please summarize the information. The details listed should be specific to your lab operations. Questions 1 and 2 should have the steps for your spill response and exposure response. Some PIs copy and paste the steps for spills from the SOP they use. If you have questions about the level of detail needed feel free to reach out to the IBC office.</p> <p>10) In the liquid waste section, can you verify that the treated waste is poured into a bag and placed into the trash? Typically liquid waste is disposed of in another manner, such as if it is culture media, it typically can be poured down the drain unless it contains a hazardous chemical.</p> <p>11) In the liquid and solid waste sections, please note that waste must be placed into a red biohazard bag during collection and treatment. The treated waste in the red bag must then have the treated waste sticker added and placed into a black bag. The current section states "preferably red or black".</p> <p>Office Note: I have added a statement in the solid waste section based on what you put on the plant page that addresses the plant materials explicitly as the committee often asks for this. Please feel free to review and make any changes needed, or let me know and I can adjust it for you. Quoted here: "Waste such</p>	

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		as seeds, pollen, and other plant materials (leaves, stems, roots, etc...), and soil will be autoclaved in the lab or devitalized in the phytotron."	
Protocol Overview	0003	1) Please remove "WE DO NOT USE ANY VECTOR or PLASMID for gene editing of plants in this project." to improve clarity. The RNP is enacting genetic changes, and the aforementioned statement may cloud the objectives.	
Vectors/ Plasmids	0003	1) Please remove "No vector will be used in this project." to improve clarity. The RNP is enacting genetic changes. 2) Please clarify what the role of the PDS gene is for the plants.	
Plants and Macroscopic Fungi	0003	1) Sorghum and cotton are highly cross-pollinated species. While the project does not involve the development of transgenic plants, it does aim to generate gene-edited lines that may have the potential to cross-pollinate with other lines cultivated in the same greenhouse facility. The investigators have not provided details on the measures to prevent unintended cross-pollination. Please clearly outline the specific strategies and containment procedures that will be implemented to mitigate this risk.  This can be done in the "Describe applicable containment, housing, disposal, pest management, breeding control, seed capture, and biocontainment practices involved in the work with the material(s)." section for each plant's entry.	Answered
Risk Management	0003	1) In the "Bleach Solution:" section, please correct contact time for both solutions/concentrations listed. This should be the time required for the disinfectant to be in contact with the surface or material. 2) Is liquid waste discarded by pouring into bags and throwing into the trash? Solid waste and liquid waste seem to need to be differentiated more. 3) In the solid and liquid waste section, please include this information as a step-by-step procedure, as it may be challenging to understand which aspects of the section should be implemented at what time (ex., Tightly sealing bags should not	Answered

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		<p>be done prior to autoclaving, but can be done before disposal. Currently it is unclear when this is called for as parts of the "baggage and labeling" portion occur across the entire waste collection and treatment process).</p> <p>4) In the spill response of the "Describe emergency procedures." section, the disinfectant should be stated with contact time.</p>	

**VOTE:**

- ☐ A motion was made to table the application pending additional information from the PI:
- ☐ A motion was made to defer the application back through the DMR process.
- ☒ A motion was made to approve the registration as is.
- ☐ A motion was made to approve the registration pending the following changes or conditions to be met: