Muse Safety Protocol Checklist

Directions: Use this guidance checklist to ensure that you have all required parts entered and information captured in Muse for your Protocol. Please contact IBC@uams.edu if you have any questions.

Required Muse Additions: Copy & Paste #1-10 Below

The following headings **must** be added to either or both the **Biohazards #2** and **Chemical Summary #2** sections to ensure all safety information is captured. It is recommended to copy and paste the following headings into the text box and describe them as applicable to your research:

1. **Description:** how the hazards indicated in your research will be used, what testing will be performed, etc. (Note: If not already described in another section, such as Summary of Research).

2. **Transportation of Hazards**: Primary & Secondary containment, leakproof, biohazard symbol or other appropriate hazard communication, and labelled with agent name, PI name, and PI emergency phone number (spill kit location if necessary).

3. **Centrifugation & Aerosol Prevention**: safety cups/sealed rotor use in centrifuge and vortex use.

4. **Hazard Containment & Precautions**: when will a BSC/CFH be used, PPE required for work, & splash precautions. Describe the Administrative Controls, Engineering Controls, and PPE for each step in your experiment.

5. **DOT/IATA Shipping**: DOT/IATA requirements are met & appropriate containers are used. Indicate who will be performing shipping and ensure their training is documented in 'Protocol Team Members'. (Can mark N/A if not applicable).

6. **Signage:** Biohazard Signs (Agent Name, Hazards, & PPE Required), Agent Labelling, and Biohazard Door Sign (Agent Name, PI Name, PI Emergency Contact Phone Number, and Required PPE) are on the laboratory door and equipment used.

7. **Animal Use:** If applicable, describe how the agents will be used in animal (which biohazard will be used in which strain). Also indicate the **AUP** number or if an **AUP** has been submitted.

8. **Animal Facilities**: Cage Cards, Door Signs, & PPE Use for DLAM. Please also list the **hazardous chemicals** that cage cards will be used for. (Note: Cage cards must be used for all BSL-2 or higher biological hazards and for all hazardous chemicals).

9. **Biosafety Cabinet/Chemical Fume Hood:** Indicate the Biosafety Cabinet (BSC) and/or Chemical Fume Hood (CFH) location and certification date in this section for all safety cabinets used.

10. **Laboratory Specific Training:** Indicate who will train the laboratory staff on specific lab procedures for all procedures in this experiment. Also indicate how the training will be documented and if there will be annual retraining.

Note: Can upload training documentation in Protocol Team Member: #3 External Team Member Information or in Supporting Documents.

Note: BSCs are not certified by UAMS. BSCs are certified by an external company.

Note: Recommend using tables A- Laboratory Facilities and B- Animal Facilities from your paper protocol, if applicable.

Section Overviews

Note: Depending upon your agents, different sections will become available. Please complete all sections and mark any sections that are not applicable as '**N/A**'. Please avoid leaving blanks in your protocol. Use the Navigation pane to move from section to section as needed.

Basic Information & Funding:

Basic Information:

☐ 1. Title of Protocol	**Long descriptive title** (Title of Protocol & Short Title can be the same).
☐ 2. Short Title	**Title that is displayed in Muse**. If applicable, include the BP# in parenthesis at the end (BP#). **Note:** example, '**Infection Response (BP#)**'
☐ 3. Summary of Research (Abstract)	In plain language describe exactly what you are doing. Ensure to include the **who**, **what**, **when**, **where**, and **why** of your experiment or clinical trial. Please indicate what hazard precautions will be used, such as a BSC. Also indicate the agents to be used, goals of your research, and research methods to be performed. **Note:** Can use 'Abstract' from old Paper Protocol, can copy and paste.
☐ 4. Select Appropriate Safety Review	Select **Biosafety**. **Note**: Only select Radiation Safety if you are working solely with radiation and no other hazards.
☐ 5. Principal Investigator	Type and select the Principal Investigator's **name**.
☐ 6. Research Location	Select which **facility** your research will be performed at or performed at mostly.

Protocol Team Members:

☐ 1. Identify Team Members	Click **'+Add'** to add your team members (*by required): ☐ *1. Select the protocol team member, search using their **name** (last name, first name). ☐ *2. Select their **role**(s) in research. ☐ *3. Type in additional roles or titles, if applicable.

	☐ *4. Indicate if the team member is involved in laboratory or research procedures. **Note**: *Can leave #2 blank, but then #3 is required.
☐ 2. Team Member Training	**UAMS and CITI Trainings will auto populate** (may need to click 'Save'). Ensure trainings are up-to-date and meet all of your experiment's training needs.
☐ 3. External Team Member Information	Use this to capture **Arkansas Children's (ACH) Trainings, Veteran's Affairs (VA) Trainings,** and **Other External Training Certificates**. **Note:** Please use the 'Arkansas Children's Training Documentation' Form for ACH trainings.

Funding Sources:

☐ 1. Funding Organization	Click **'+Add'** and select the appropriate **funding organization**. Also, upload funding documents or files in #4 (this section is optional: use 'UAMS' as optional funding source). **Note:** Can select - Data Not Available - if the funding source is not listed.
☐ 2. Sponsor's funding ID	Can type in the funding ID or the Name of the Funding Source if indicated - Data Not Available – in #1. **Note:** Questions #2 and #3 are free text boxes so you can write in any necessary information.

Biosafety Summary:

Biosafety Summary:

☐ 1. Items involved in the protocol	Select all of the **agents** involved in the protocol. If you select 'Other', describe the item in the text box. **Note**: select '**Other'** if your protocol involves only hazardous **chemicals** or drugs. **Note:** select '**Human Research Participants**' if you are collecting human samples and processing them in a research laboratory or performing a clinical trial/gene therapy trial.

	Note: if human samples are de-identified (patient identifiers have been removed) and are being acquired from another researcher or biorepository that does not require IRB purview, the '**Human Research Participants**' section is not required.

Agents, Toxins, & Microorganisms:

Note: Please email Biosafety Officers (kaloyd@uams.edu and dmilke@uams.edu) if you need an agent, chemical, or a room number added.

Tissues, Blood, or Body Fluids:

☐ 1. List agent, type, and source of all Tissues, Blood, and Body Fluids.	Click **'+Add'** to add Tissues, Blood, or Body Fluid Agents (*by required): ☐ *1. Select the **Agent**. ☐ *2. Select the **Biosafety Level** (BSL). ☐ *3. Describe the **use** of the Agent: describe how the agent will be used from start to finish. Where it will be collected (clinical or lab space), how many patients (if applicable; can approximate), processed (BSC, centrifuge, vortex used?), tested, shipped, etc., and how. ☐ *4. Where are you obtaining the **material from**: example, humans, animals, patients, manufacturer, etc. ☐ *5. Select the **storage** locations. **Note**: use the **%** to search for your room number. Example: %1234 ☐ *6. Select the **usage** locations. ☐ 7. Indicate the **supplier** (if applicable): the **IRB number** of the source protocol/laboratory or who the manufacturer is. ☐ 8. Indicate maximum **quantity** stored in the lab space, if known. ☐ 9. Indicate **personnel** that will be handling the material, if applicable: example, this field is necessary if only certain members of the research team are trained or have the qualifications to handle the agent. ☐ 10. Experimental **concentration**, if applicable. ☐ *11. Is agent used in animals?

	☐ *12. Is agent used in humans? ☐ *13. Is agent recombinant or synthetic?
☐ 2. Describe any tissues transplanted between species, if applicable.	Indicate if you are transplanting tissues or mark **N/A**.
☐ 3. Describe the quantity of tissues and volumes of fluids to be used.	Indicate the **quantities of tissues** and volumes to be used throughout your experiment, in detail: Example: 3 mL of blood will be collected from approximately 50 patients for a maximum quantity of 150 mL.

Primary Cells or Cell Lines:

☐ 1. List agent, type, and source of all Primary Cells or Cell Lines.	Click **'+Add'** to add Primary Cells or Cell Lines (*by required): ☐ *1. Select the **Agent**. ☐ *2. Select the **Biosafety Level** (BSL). ☐ *3. Describe the **use** of the Agent: describe how the agent will be used from start to finish. Where it will be collected (clinical or lab space), how many patients (if applicable; can approximate), processed (BSC, centrifuge, vortex used?), experimental use, etc., and how. ☐ *4. Where are you obtaining the **material from**: example, humans, animals, patients, manufacturer, etc. ☐ *5. Select the **storage** locations. **Note**: use the **%** to search for your room number. Example: %1234 ☐ *6. Select the **usage** locations. ☐ 7. Indicate the **supplier** (if applicable): the **IRB number** of the source protocol/laboratory or who the manufacturer is. ☐ 8. Indicate maximum **quantity** stored in the lab space, if known. ☐ 9. Indicate **personnel** that will be handling the material, if applicable: example, this field is necessary if only certain members of the research team are trained or have the qualifications to handle the agent.

	☐ 10. Experimental **concentration**, if applicable. ☐ *11. Is agent used in animals? ☐ *12. Is agent used in humans? ☐ *13. Is agent recombinant or synthetic?
☐ 2. List other mammalian species cell lines.	Indicate which, if any, of your cell lines listed above are non-human mammalian cells. Also list any cell line transduced derivatives or mark **N/A**.
☐ 3. List other non-mammalian species cell lines.	Indicate which, if any, of your cell lines listed above are non-mammalian cells or mark **N/A**.
☐ 4. Identify cultures in volumes over 10 liters.	Indicate if you have any cultures more than 10 liters or mark **N/A**.

Bacteria, Yeasts, Fungi, or Parasites:

☐ 1. List agent, type, and source of all Microorganisms: Bacteria, Yeasts, Fungi, or Parasites.	Click **'+Add'** to add Tissues, Blood, or Body Fluid Agents (*by required): ☐ *1. Select the **Agent**. ☐ *2. Select the **Biosafety Level** (BSL). ☐ *3. Describe the **use** of the Agent: describe how the agent will be used from start to finish. ☐ 4. Indicate the **strain**, if applicable. ☐ *5. Where are you obtaining the **material from**: example, humans, animals, patients, manufacturer, etc. ☐ *6. Select the **storage** locations. **Note**: use the **%** to search for your room number. Example: %1234 ☐ *7. Select the **usage** locations. ☐ 8. Indicate the **supplier** (if applicable): who the manufacturer is. ☐ 9. Indicate maximum **quantity** stored in the lab space, if known. ☐ 10. Indicate **personnel** that will be handling the material, if applicable: example, this field is necessary if only certain members of the research team are trained or have the qualifications to handle the agent.

	☐ 11. Experimental **concentration**, if applicable. ☐ *12. Is agent used in animals? ☐ *13. Is agent used in humans? ☐ *14. Is agent recombinant or synthetic?
☐ 2. Describe other microorganisms	**Optional**: describe other microorganisms being used that are not primary parts of the experiment or mark **N/A**. **Note**: Can include other microorganisms in the above section.

Viruses or Prions:

☐ 1. List agent, type, and source of all Viruses or Prions.	Click **'+Add'** to add Tissues, Blood, or Body Fluid Agents (*by required): ☐ *1. Select the **Agent**. ☐ *2. Select the **Biosafety Level** (BSL). ☐ *3. Describe the **use** of the Agent: describe how the agent will be used from start to finish. ☐ 4. Indicate the **strain**, if applicable. ☐ *5. Where are you obtaining the **material from**: example, humans, animals, patients, manufacturer, etc. ☐ *6. Select the **storage** locations. **Note**: use the **%** to search for your room number. Example: %1234 ☐ *7. Select the **usage** locations. ☐ 8. Indicate the **supplier** (if applicable): who the manufacturer is. ☐ 9. Indicate maximum **quantity** stored in the lab space, if known. ☐ 10. Indicate **personnel** that will be handling the material, if applicable: example, this field is necessary if only certain members of the research team are trained or have the qualifications to handle the agent. ☐ 11. Experimental **concentration**, if applicable. ☐ *12. Is agent used in animals? ☐ *13. Is agent used in humans?

	☐ *14. Is agent recombinant or synthetic?
☐ 2. Describe other Viruses or Prions	**Optional**: describe other viruses or prions being used that are not primary parts of the experiment or mark **N/A**. **Note**: Can include other viruses or prions in the above section.

Select Agents & Toxins or Toxins:

☐ 1. List agent, type, and source of all Select Agents & Toxins or Toxins.	Click **'+Add'** to add Tissues, Blood, or Body Fluid Agents (*by required): ☐ *1. Select the **Agent**. ☐ *2. Select the **Biosafety Level** (BSL). ☐ *3. Describe the **use** of the Agent: describe how the agent will be used from start to finish. ☐ *4. Where are you obtaining the **material from**: example, humans, animals, patients, manufacturer, etc. ☐ *5. Select the **storage** locations. **Note**: use the **%** to search for your room number. Example: %1234 ☐ *6. Select the **usage** locations. ☐ 7. Indicate the **supplier** (if applicable): who the manufacturer is. ☐ 8. Indicate maximum **quantity**, if known. ☐ 9. Indicate **personnel** that will be handling the material, if applicable: example, this field is necessary if only certain members of the research team are trained or have the qualifications to handle the agent. ☐ 10. Experimental **concentration**, if applicable. ☐ *11. Is agent used in animals? ☐ *12. If this is a select agent or toxin, has it been registered with the **DSAT (Department of Select Agents or Toxins)**? ☐ *13. Is agent used in humans? ☐ *14. Is agent recombinant or synthetic?

☐ 2. Does this protocol involve an excluded select agent or toxin?	Indicate **yes** or **no** as appropriate.
☐ 3. Does this protocol involve any select agents or toxins in exempted amounts?	Indicate **yes** or **no** as appropriate.
☐ 4. Describe the volumes of cultures to be used for any select agents or toxins.	If needed, indicate in detail the quantities of Select Agents & Toxins or Toxins or mark **N/A**.

Biohazards:

☐ 1. Summary of each agent, toxin, or microorganism that will be used in this protocol.	Verify that **all biohazard agents** that will be used in your protocol are listed. **Note:** Chemical Agents are captured in another section.
☐ 2. Provide a description of any agents, toxins, or microorganisms indicated above.	Add the following required subheadings (or add to Chemical Summary section #2): ☐ 1. **Description:** how the hazards indicated your research will be used, what testing will be performed, etc. (Note: If not already described in another section, such as Summary of Research). ☐ 2. **Transportation of Hazards**: Primary & Secondary containment, leakproof, biohazard symbol or other appropriate hazard communication, and labelled with agent name, PI name, and PI emergency phone number. ☐ 3. **Centrifugation & Aerosol Prevention**: safety cups/sealed rotor use in centrifuge and vortex use. ☐ 4. **Hazard Containment & Precautions**: when will a BSC/CFH be used, PPE required for work, & splash precautions. Describe the

	Administrative Controls, Engineering Controls, and PPE for each step in your experiment. ☐ 5. **DOT/IATA Shipping**: DOT/IATA requirements are met & appropriate containers are used. Indicate who will be performing shipping and ensure their training is documented in 'Protocol Team Members', or mark **N/A** if not applicable. ☐ 6. **Signage:** Biohazard Signs (Agent Name, Hazards, & PPE Required), Agent Labelling, and Biohazard Door Sign (Agent Name, PI Name, PI Emergency Contact Phone Number, and Required PPE). ☐ 7. **Animal Use:** If applicable, describe how the agents will be used in animal (which biohazard will be used in which strain). Also indicate the **AUP** number or if an **AUP** has been submitted. Indicate **N/A** if this is not applicable. **Note:** Ensure to indicate animal use in the agent information for each biohazard. ☐ 8. **Animal Facilities**: Cage Cards, Door Signs, & PPE Use for DLAM. Indicate **N/A** if this is not applicable. ☐ 9. ***Biosafety Cabinet/Chemical Fume Hood:** Indicate the Biosafety Cabinet (BSC) and/or Chemical Fume Hood (CFH) location and certification date in this section for all BSC and CFH used. Indicate **N/A** if this is not applicable. **Note**: BSC are not certified by UAMS. BSC are certified by an external company.

	☐ 10. ***Laboratory Specific Training:** Indicate who will train the laboratory staff on specific lab procedures for the biohazards in this experiment. How the training will be documented and if there will be annual retraining. **Note**: Can upload training documentation in Protocol Team Member: External Team Member Information or in Supporting Documents. **Note**: Recommend using tables B, C, & D from Section V: Research Elements from your paper protocol, if applicable.

Recombinant & Synthetic Nucleic Acids:

Recombinant or Synthetic Nucleic Acids Usage:

☐ 1. Does research with recombinant or synthetic nucleic acids involve the use of.	Select the appropriate NIH Guideline for your research involving recombinant or synthetic nucleic acids (r/sNA). **Note**: see the NIH Guidelines for more information or if you have a past paper protocol, section A. iii. **Note**: Common NIH sections used are: • **Section III-C-3:** Recombinant use in Humans; IRB approval also required. • **Section III-D-1:** Risk Group 2,3, 4, or restricted agents as host-vector systems. • **Section III-D-3:** Use of infectious viruses. • **Section III-D-4:** rDNA experiments with whole animals. • **Section III-E-1:** BL-1 containment; generated nucleic acids contain no more than 2/3rd genome of eukaryotic virus. • **Section III-F (Exempt):** unable to replicate, exist contemporaneously in nature, uses K-12 *Escherichia coli* or derivatives, generation of BL-1 transgenic rodents via breeding, etc.
☐ 2. If none of these apply, describe.	If you did not select an appropriate NIH Guideline above, indicate why and describe your research. **Note**: Write N/A or leave blank if this text box is not applicable.

Recombinant or Synthetic Nucleic Acid Work Description:

☐ 1. Describe any work involving recombinant or synthetic nucleic acid molecules. Include information about host-vector systems, genes, and procedures.	Give an overview of <u>what</u> you are doing with recombinant or synthetic nucleic acids (r/sNA) and the **risk attenuation**. **For example**: Cloning, PCR, expression in a microbe, use in a tissue culture, or use in an organism.
☐ 2. For each experiment, list genes, inserts, gene products, and key regulatory elements to be cloned.	**List** the following types of items to be cloned in your research in the text box: ☐ **Genes** (explain acronyms) ☐ **Inserts** ☐ **Gene Products** ☐ **Key Regulatory Elements**
☐ 3. Provide a brief description of gene activity and indicate the species of origin for each.	Indicate the following for all **genes** listed above: ☐ Description of **Gene Activity:** state what each Gene listed above does. **Note**: Give the Nature of Insert or Protein Expressed (Toxin, antibiotic resistance/ selection marker, virulence factor, reporter, oncogene, transcription factor, etc.) ☐ Species of Origin (**Genus and species, strain**) for <u>each</u> Gene Activity listed. **Note:** Use the table in Section A.i. of your past paper protocol, column 3 and column 1, if applicable.
☐ 4. Describe all vectors (plasmids, viruses, RNA/DNA constructs) to be used	List out all vectors to be used and describe what they will be used for: Gene Transfer Method, Vector & Biosafety Level, Vector Function (cloning, protein expression, etc.), & Risk Attenuation. **Note:** Use the table in Section A.ii. of your past paper protocol, if applicable.
☐ 5. Upload vector map.	Upload your vector map, if available. **Note 1**: If you are using/generating multiple r/sNA, number them and use the corresponding numbers throughout the 'Recombinant Nucleic Acid Work Description' section for the corresponding vectors, hosts, vector maps, etc.

	Note 2: For multiple vector maps, copy and paste them into a Word document, print to PDF, and then upload the PDF file.
☐ 6. For each experiment identify all applicable host systems to be used.	List & explain the use of each of the applicable items: ☐ **Packaging Systems** (Tables A.i-iii from paper protocol) ☐ **Microbes** (Table B from paper protocol) ☐ **Tissue/Cell Culture** (Table C from paper protocol) ☐ **Plant/Animal** (Table D from paper protocol)
☐ 7. Describe any attempts to express foreign genes from living organisms.	Indicate in detail foreign genes to be expressed & list what organism they are from.
☐ 8. List any proteins produced.	List proteins.

Note: If you have a previous paper protocol, ensure all information from Section A is captured in the Recombinant Nucleic Acid section of Muse.

Human Gene Transfer/Human Clinical Trials:

Note: if human samples are **de-identified** (patient identifiers have been removed) and are being acquired from another researcher or biorepository that does not require IRB purview, then this section is **not** required.

Note: this section is **required** if you are performing any work that falls under IRB purview, such as collecting human samples and processing the samples in a research laboratory or performing a clinical trial/gene therapy trial.

☐ 1. Provide a brief description of the overall goals and research activities.	List or indicate the goals of your research (why are you doing this study).
☐ 2. Provide a summary of biosafety-relevant preclinical and clinical studies associated with this protocol **Attach Summary Documents**	Describe any **biosafety** related information for your study. **Note**: Click the ? button for help information (attach supporting documents and lab procedures as needed). **Note**: if this protocol is only for prep and shipping of human specimens, indicate that the collection will be performed in the clinical area and that lab staff

	are following and have been trained in **safe bloodborne pathogen handling procedure**.
☐ 3. Provide a description of the materials.	List any materials used and describe their use. **Note**: If only shipping human body fluids or tissue, indicate that.
☐ 4. Describe specific procedures for clinical monitoring of the biohazard used in the protocol (e.g. potential for shedding)	List procedures for monitoring the patient or patient samples for hazards, such as **shedding, fever watch, lab screenings for disease, etc**. **Note**: if this protocol is only for prep and shipping of human specimens, this section may be '**no clinical monitoring**' or '**only monitored for standard bloodborne pathogens**'.
☐ 5. Attach all relevant standard operating procedures (SOPs).	Upload any other SOPs or brochures for this clinical trial (can upload multiple files). **Note**: Can upload PCRU SOP here or in 'Supporting Documents'.
☐ 6. Attach clinical protocols.	Upload the clinical protocols or the study details here (can only upload one file).
☐ 7. Additional Documents.	Any additional documentation, IRB approval letter, etc. can go here.
☐ 8. Has IRB review been initiated in CLARA?	Indicate **yes** or **no** as appropriate. **Note**: Ensure to complete the **Manage Related IRB Studies** to input information about your Human Clinical Trial, located on your protocol's homepage.
☐ 9. CLARA Number.	Type in your CLARA number(s) (**required**). **Note**: For multiple CLARA numbers, please list them. Example: 1,2,3… ,n.

Animals and Genetically Modified Animals:

Animals:

Note: Please **disregard** the statement, "If no related IACUC protocols".

☐ 1.a. Identify the species to be used (**click the three dots**).	Select each of the **animal species** to be used. **Note**: email Biosafety Officers if you need to add a species.

☐ 1.b. Identify the locations where animals are being housed or used (**click the three dots**).	Select the **location**(s) that the animals listed above will be housed and used. **Note**: use the **%** to search for your room number. Example: %1234
☐ 2. Are the animals used in the experiment immunocompromised?	Indicate **yes** or **no** as appropriate.
☐ 3. If yes, describe how.	List **all animal strains** to be used and indicate which ones are immunocompromised. Describe how each animal strain will be used.
☐ 4. Which of the following present exposure risks to the protocol team members or animal care personnel?	Select each that applies for your animals (consider the biohazards) for any animal handling staff, such as DLAM or your laboratory team. **Note**: if **Other** is selected, please describe what the other hazard is in the Biohazard or Chemical Summary section.

Genetically Modified Animals: DNA Source

☐ 1. Describe the transgene and remaining vector sequences.	List each transgenic animal, their **transgenes**, and remaining vector sequences. **Describe the use or purpose of each.** **Note:** If the animals are generated by **breeding only**, please indicate that breeding is performed not transgenic (lentiviral vector work).
☐ 2. Will you be purchasing, breeding, or obtaining transgenic rodents from an external laboratory or have you done so in the past?	Have you or will you purchase or receive transgenic rodents for this protocol? Indicate **yes** or **no** as applicable.
☐ 3. Will this protocol involve creating a transgenic strain on site at a BSL-1 containment level?	Are you generating BSL-1 transgenic rodents in your lab space in this protocol? Indicate **yes** or **no** as applicable.

☐ 4. What is the source of the DNA?	Select all that apply.
☐ 5. Are human or animal **pathogens** to be used as a host-vector system?	Indicate **yes** or **no** as applicable.
☐ 6. Does this experiment use viruses?	Indicate **yes** or **no** as applicable.

Gene Transfer: Transgenic Strain

Note: Only complete this section if **you are creating transgenic animals** in your laboratory. Do **not** complete this section if you are purchasing or receiving the transgenic animal strain(s) from a supplier or another laboratory.

☐ 1. Describe why it is necessary to generate transgenics to conduct this research	Relevant to this protocol, **why are you creating a transgenic animal strain**.
☐ 2. Describe the goals of the research and all procedures used.	Briefly describe **how the transgenic animal strains generated help achieve your research goals**. List all procedures and all biohazards to be used with the transgenic animals.
☐ 3. Describe how this research relates to the NIH Guidelines for Research Involving rDNA.	Describe the **animal genome alteration** and the Biosafety Level (BSL), does this fall under Section III-E-3 or III-D-4. **Note:** Click the NIH Guidelines for more information and help (Read Section III-E-3: Experiments Involving Transgenic Rodents).
☐ 4. Does this protocol involve the alteration of the germ line of the animal?	Indicate **yes** or **no** as appropriate.
☐ 5. How will the DNA be introduced?	Describe **how the DNA will be introduced to create the transgenic animal**, such as DNA microinjection, embryonic stem cell-mediated gene transfer, or retrovirus-mediated gene transfer.

Gene Transfer: Virus

☐ 1. Do the experiments involve formation of	Indicate **yes** or **no**.

rDNA molecules containing > 50% of the genome of any eukaryotic viruses of the same family?	**Note:** Ensure the appropriate NIH Guideline is selected in the 'Recombinant or Synthetic Nucleic Acids Usage' section.
☐ 2. Do the experiments involve the use of infectious human or animal viruses?	Indicate **yes** or **no**.
☐ 3. Do the experiments involve the use of a defective human or animal virus in the presence of a helper virus?	Indicate **yes** or **no**.

Plants:

Transgenic Plants:

☐ 1. Does your protocol involve the use of transgenic plants	Indicate **yes** or **no** as appropriate.
☐ 2. If yes, provide a description of each transgenic plant species.	Describe each **transgenic plant species** used: how you will use in your protocol, transport, containment (BSC), disinfect, store, quantity, biosafety level, etc.

Risk Management:

Risk Group and Containment Practices:

☐ 1. What is the highest **risk group** level of the biological agents and materials you will use in the proposed research?	Classify the **pathogens or biohazard agents** in your protocol as risk group 1-4. Choose the highest risk group based upon your pathogen or biohazard agent used. **Note**: Most UAMS/ACRI protocols use Risk Group 2 (RG2) pathogens. Risk Group does not correspond with Biosafety Level. Click the blue link to use the

	NIH Guidance for help finding your biohazard agent Risk Group. **Note**: For example, HIV is a Risk Group 3 virus.
☐ 2. What are the highest biosafety containment practices required for the research activities covered by this protocol?	For your protocol, **select only the biosafety levels that apply** to the practices that you are using to contain the biohazards (rDNA, plants, animals, etc.). **Note**: Biosafety Levels are the handling and containment practices that you use to contain the pathogen or biohazard agent. **Note**: For example, rDNA use in Mice that uses RG-2 agents, could be handled at BSL-2 (for the virus), ABSL-2 (for the infected animals), BL-2 (for the rDNA), and BL2-N (for the animals with rDNA). **Note**: Use the **NIH Guidelines** for containment requirements, such as Section III-D-4: Experiments Involving Whole Animals, a containment of BL2 or BL2-N is required.

Exposure Assessment and Protective Equipment:

☐ 1. Describe consequences of exposure or release of agents used to humans, animals, and plants.	For each agent listed in your protocol describe what to do if you have a skin, mucous membrane, eye, inhalation, or other exposure: ☐ **Biohazard Agents:** for all listed in Agents, Toxins, & Microorganisms section ☐ **r/sNA or rDNA:** for all listed in Recombinant & Synthetic Nucleic Acids section ☐ **Animals**: for all listed in the Animals section **Note:** Ensure that all potential exposures, such as animal bedding (checked in #4 of the 'Animals' section) are addressed. ☐ **Plants:** for all listed in the Plants section ☐ **Chemicals/Drugs:** for all listed in the Custom Pages **Note:** use or cite the UAMS Biosafety Manual Can use excerpt in your UAMS protocol: **Skin, Mucous Membrane, or Injury Exposure:** All exposures to recombinant or synthetic nucleic acid molecules or recombinant pathogens must be reported to the laboratory supervisor or PI immediately, as well as the Biological Safety Officer

	(501-686-5536). If the exposure results in an emergency, call the UAMS Call Center at 501-526-0000 or 911 to request help. Otherwise, the following steps should be taken: If there is an agent-specific protocol for exposure, such as those for HIV or Hepatitis B, follow those protocols. For skin contact exposure or injury with a contaminated instrument: • Thoroughly wash the area with soap and water. Do not squeeze the wound to induce bleeding. • Avoid using abrasive chemical soaps or disinfectant washes, as they can cause skin abrasions and a possible additional route of entry for the agent. • Cover the wound with sterile dressing. • For mucous membranes (e.g., eyes, mouth), flush with water for a minimum of 15 minutes. • Contact UAMS Student and Employee Health as soon as possible after exposure • Exposed personnel must complete the Employee/Student Injury and Incident Report (I&I) Form. • Employees of UAMS must call the Company Nurse Injury Hotline at 1- 855-339-1893 as soon as possible after injury or exposure. • During normal business hours, exposed individuals should contact the Preventive Occupational Environmental Medicine Clinic at 501-686-6565 (open 8 a.m. to 4:30 p.m.) • After hours, exposed individuals should contact the UAMS Emergency Department at 501-686-2085 for evaluation. Any exposures to recombinant DNA must be reported to the following: • Principal Investigator or Laboratory Director—Immediately • Biological Safety Officer (501-686-5536)—Immediately • Institutional Biosafety Committee (IBC)—May be reported through Biological Safety Officer • NIH/OBA—Report will be coordinated by the IBC Example: Cell lines and other potentially infectious material (OPIM): potential exposure could cause infection with a bloodborne pathogen.

	-Eyes: Flush with water for 15 minutes. -Skin: Wash with soap and water. -Mucous Membrane: Flush with water for 15 minutes. Puncture or Needle Stick: Wash with soap and water. For all exposures immediately seek medical assistance at Student and Employee Health (SEHS)/ Preventive, Occupational and Environmental Medicine (POEM) Clinic, Central Building G600. If after-hours, a holiday, or if it is an Eye Exposure, go to the UAMS Emergency Department. As you are able, complete an Incident & Injury Form on the OH&S website, inform your supervisor/PI of the incident, and call the Nurse Hotline, if needed (must complete as soon as possible, within 24-48 hours of the incident). **Note**: Biosafety Officers must be informed immediately of all rDNA and infectious pathogen exposures.
☐ 2. Indicate the personal protective equipment that will be used.	Select all PPE that will be used at any point in your protocol.
☐ 3. If other, specify.	☐ Indicate **Other PPE**. **Note:** Also use this space to indicate if **certain PPE** selected above will **only be used during certain procedures**, such as eye protection will only be used when procedures with a splash risk are performed. **Note:** Also use this space to indicate what **type of respirator** will be used, such as N-95, PAPR, CAPR, etc.

Dual Use Research of Concern:

☐ 1. Dual use experiment categories used in this research	Select all that apply. **Note**: most UAMS/ACRI protocols are 'None of the above'. **Note**: Any select agent work, work that increases virulence of a pathogen, or could potentially cause harm to public health and safety may be dual use research of concern and must have the appropriate oversight and documentation.
☐ 2. Explain why you believe this protocol is	Explain your above selection.

or is not dual use research of concern	**Note**: For '**None of the above**' the following statement can be used, if it is applicable to your protocol: *No agents are being used that are subject to the US Government DURC policies and no laboratory procedure performed will increase the harmful consequences of any agent or toxin present.*

Waste Management:

☐ 1. Describe the process for decontaminating biological waste.	For each agent listed in your protocol describe how the waste generated will be disposed of for all that apply: ☐ **Surfaces & Equipment** used in your research. ☐ **Liquid Biohazard Waste:** for all listed in Agents, Toxins, & Microorganisms section. ☐ **Solid Biohazard Waste:** for all listed in Agents, Toxins, & Microorganisms section. ☐ **r/sNA or rDNA:** for all listed in Recombinant & Synthetic Nucleic Acids section. ☐ **Animal Wastes & Animal Bedding**: for all listed in the Animals section. **Note:** Ensure that all potential wastes, such as animal bedding, is considered. ☐ **Plants:** for all listed in the Plants section. ☐ **Chemicals/Drugs:** for all listed in the Custom Pages. ☐ ***Disinfectant and Contact Time:** must indicate for all disinfectants used. Example, 10% bleach for a minimum of 20 minutes (recommend wiping with 70% ethanol after to prevent corrosion). ☐ ***Autoclave time & temperature:** if applicable. Example, 121°C and 15 psi for 20 minutes. ☐ ***Sharps:** disposed of in appropriate Sharps containers. **Note:** use or cite the UAMS Biosafety Manual Decontamination (Section 11) & Waste Management (Section 13). Also consider liquid vs.

	solid biohazard waste. Can use excerpt in your protocol: 13.4.1 Sharps Waste All sharps must be placed into properly labeled sharps containers or other rigid, puncture-proof containers. Sharps containers must not be filled more than 2/3 full. Make sure the container is sealed, labeled, and intact. When filled, request pickup of sharps containers by contacting the UAMS Biohazard Waste Pickup Team (501-526-0000) or requesting a pickup online: http://www.uams.edu/campusop/depts/ohs/forms/biowaste.aspx. 13.4.2 Solid Biohazardous Waste Solid waste includes cloth, plastic, and paper items that have been exposed to infectious agents hazardous to humans, animals, or plants, and solidified agarose gels. These contaminated items should be collected in appropriate biohazard waste autoclave bags. When ¾ full, loosely tie the bag closed and secure the lid on the container. Contact the UAMS Biohazard Waste Pickup Team (5001-526-0000) to request pickup or request a pickup online http://www.uams.edu/campusop/depts/ohs/forms/biowaste.aspx. 13.4.3 Liquid Biohazardous Waste Liquid biological waste should be collected in leak proof, rigid, durable containers for autoclaving or chemical disinfection. Autoclaved or chemically disinfected liquid wastes can be disposed of via the laboratory sink. Do not pour melted agarose down the drain. Allow it to cool and solidify, then dispose of it as solid waste in biohazard waste bags. Example: **All Liquid Waste** (Cell lines, rDNA, and infected material): treated for 20 minutes with 10% bleach. **All Surfaces**: wiped with 10% bleach and then with 70% ethanol and allowed to air dry. **All Solid Infectious Waste**: placed in red biohazard bags to be picked up by the Biohazard Waste team for offsite disposal. **Reusable Plastic & Glassware**: autoclaved at 121°C and 15 psi for 30 minutes. **Chemotherapy Waste**: all chemotherapy or chemical agents and any chemotherapy contaminated wastes are disposed of in yellow bags and yellow containers for off-site disposal. A

	work-order is put in for pickup by UAMS Chemical Safety. **Radiation Waste**: all radioactive waste goes in blue bags, must be secured, and then goes for off-site disposal. A work-order is put in for pickup by UAMS Radiation Safety. **Sharps**: all sharps are placed in red Sharps containers that are sealed when full and picked up by the Biohazard Waste team to be disposed of offsite. **Animal Bedding & Waste**: Cages are dumped using a dump station into red biohazard waste and incinerated offsite. All cages are autoclaved or chemically disinfected per DLAM policy to ensure sufficient sterilization. **Note:** do not autoclave anything that has been treated with bleach. **Note**: radioactive or pharmaceutical chemicals used must be disposed of properly and indicated in this section.
☐ 2. Autoclave location.	Indicate where your **autoclave** is, if use is indicated in above section. **Note:** use the above text box to indicate the location of other autoclaves if more than one is used. **Note**: Search using the % and the room number, example %123.
☐ 3. Describe the plans for decontamination in the event of a biological accident.	For each agent listed in your protocol describe how large spills, small spills, and other biological incidents will be addressed for all that apply: ☐ **Biohazard Agents:** for all listed in Agents, Toxins, & Microorganisms section ☐ **r/sNA or rDNA:** for all listed in Recombinant & Synthetic Nucleic Acids section ☐ **Animals**: for all listed in the Animals section **Note:** Ensure that all potential wastes, such as animal bedding, is considered. ☐ **Plants:** for all listed in the Plants section ☐ **Chemicals/Drugs:** for all listed in the Custom Pages

	☐ ***Disinfectant and Contact Time:** must indicate for all disinfectants used. Example, 10% bleach for a minimum of 20 minutes (recommend wiping with 70% ethanol after to prevent corrosion). ☐ ***Autoclave time & temperature:** if applicable. Example, 121°C for 15 minutes. ☐ ***Sharps:** disposed of in appropriate Sharps containers. **Note:** use or cite the UAMS Biosafety Manual Spill Procedure (Section 10). Also consider liquid vs. solid biohazard waste.

Custom Pages:

Chemical Hygiene:

☐ 1. Provide relevant hygiene information for each chemical used in the protocol.	Click **'+Add'** to add Chemicals/Drugs (*by required): ☐ *1. Select the **Agent**. **Note**: select '**Not Applicable**' if your protocol does not have chemicals and no other fields are required. ☐ *2. Describe the **physical properties** of the Agent. ☐ 3. Select the **classification**, if applicable. ☐ *4. Describe the **toxicology** of the chemical being used (use SDS). **Note**: Must indicate if chemical is a carcinogen, mutagen, teratogen, toxin, radioactive, etc. (see paper protocol section V. table E) ☐ *5. Indicate **routes of exposure** for this chemical or drug: ensure all routes of exposure are addressed in the 'Exposure Assessment and Protective Equipment' section. ☐ 6. Other **precautions**: such as, what PPE to use and if a CFH will be used. ☐ 7. **Exposure Limits**: indicate the Permissible Exposure Limit (PEL) from SDS.

	☐ 8. **Monitoring requirements**: Consider radiative chemicals (will wipe tests or badges be required). **Note**: recommend using the 'Highly Toxic Chemicals…' (table E) from your paper protocol if applicable.
☐ 2. Justify the use of the selected chemicals.	Indicate why you are using these chemicals/drugs.

Chemical Summary:

☐ 1. Identify the chemicals to be used in the protocol.	Click '**Update**' to add the locations for your Chemicals/Drugs (*by required): ☐ *1. Should already be prefilled by the Muse system (if 'Not Applicable' indicated, continue to #4) ☐ *2. Indicate the maximum **Quantity** that will be used in your experiments (Max amount administered). ☐ 3. Indicate the number of **procedures** that the chemical is involved in. **Note**: Leave blank if used in all procedures. ☐ *4. Describe the **storage location** of the chemical being used. **Note**: select '**Not Applicable'** if your protocol does not have chemicals and no other fields are required. ☐ *5. Indicate the maximum **Quantity** that will be kept on-hand. ☐ *6. Indicate the **Chemical Fume Hood** (CFH) certification date. **Note**: If the location of the CFH is different from the location in #4 or there is more than one CFH used, indicate this information in Section 2 below. ☐ *7. **Lab phone number**: put the phone number to call for emergencies. ☐ *8. **Attachments**: upload the chemical's SDS or toxicology information, if applicable. **Note**: recommend using the 'Highly Toxic Chemicals…' (table E) from your paper protocol if applicable.

☐ 2. Describe the experiment, including procedures used in the protocol.	Add the following required subheadings if not already captured in **Biohazards section #2**: **Note**: If the required subheadings are already captured, please describe the chemical use in the experiment, research goals in regards to the chemical use, and hazard mitigation (CFH and PPE use). ☐ 1. **Description:** how the hazards indicated your research will be used, what testing will be performed, etc. (Note: If not already described in another section, such as Summary of Research). ☐ 2. **Transportation of Hazards**: Primary & Secondary containment, leakproof, biohazard symbol or other appropriate hazard communication, and labelled with agent name, PI name, and PI emergency phone number. If a chemical spill kit will be used, etc. ☐ 3. **Centrifugation & Aerosol Prevention**: safety cups/sealed rotor use in centrifuge and vortex use. ☐ 4. **Hazard Containment & Precautions**: CFH use, PPE use, if administered in a BSC, & splash precautions. ☐ 5. **DOT/IATA Shipping**: DOT/IATA requirements are met & appropriate containers are used. Indicate who will be performing shipping and ensure their training is documented in 'Protocol Team Members', or mark **N/A** if not applicable. ☐ 6. **Signage:** Biohazard Signs (Agent Name, Hazards, & PPE Required), Agent Labelling, and Biohazard Door Sign (Agent

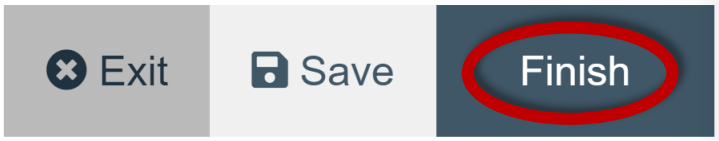
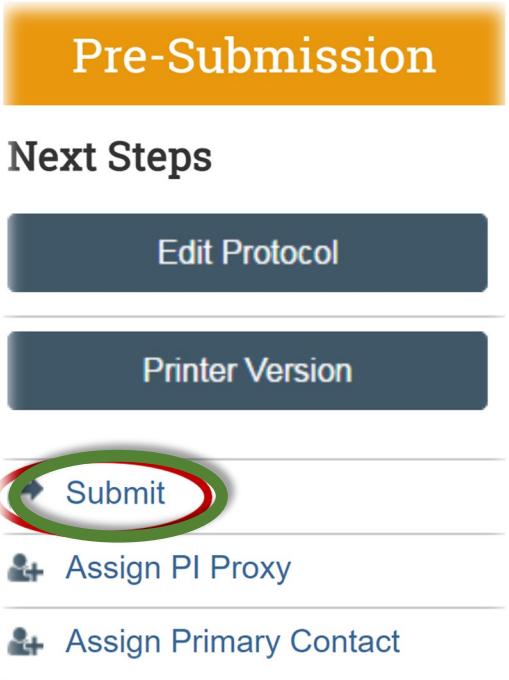
	Name, PI Name, PI Emergency Contact Phone Number, and Required PPE). ☐ 7. **Animal Use:** If applicable, describe how the agents will be used in animal (which biohazard will be used in which strain). Also indicate the **AUP** number or if an **AUP** has been submitted. Indicate **N/A** if this is not applicable. **Note:** Ensure to indicate animal use in the agent information for each biohazard. ☐ 8. **Animal Facilities**: Cage Cards, Door Signs, & PPE Use for DLAM. Indicate **N/A** if this is not applicable. ☐ 9. ***Chemical Fume Hood:** If applicable, indicate the Chemical Fume Hood (CFH) location and certification date in this section for all CFH used (if not captured in section #1 above). **Note**: CFH are certified by UAMS, call the call center (501-526-0000) if yours need certification. **Note**: If not previously captured, also indicate the **BSC locations and certification dates** here. BSC are not certified by UAMS. BSC are certified by an external company. ☐ 10. ***Laboratory Specific Training:** If applicable, indicate who will train the laboratory staff on specific lab procedures for the biohazards in this experiment. How the training will be documented and if there will be annual retraining. **Note**: Can upload training documentation in Protocol Team Member: External Team Member Information or in Supporting Documents.

	Note: Recommend using tables B, C, & D from Section V: Research Elements from your paper protocol, if applicable.
☐ 3. Describe the methods used.	List any established methodologies that you will be performing to meet your procedural goal(s) indicated above, such as IP injection into rats, oral gavage into mice, LeBlanc method, distillation, etc. **Example**: Method 1: subcutaneous mouse injection of chemical X. **Note**: recommend using the 'Highly Toxic Chemicals…' (table E) from your paper protocol if applicable.
☐ 4. Will liquid N_2 or cryogenic liquid be used?	Indicate **yes** or **no** as appropriate.

Supporting Documents:

☐ 1. Upload **Paper Protocol.**	If applicable, upload your most recent **Paper Protocol** that corresponds with this Muse protocol.
☐ 2. Upload **Approval Letter**.	If applicable, upload your most recent **Approval Letter** that corresponds with this Muse protocol.
☐ 3. Upload any **Supporting Documents**.	Upload any necessary supporting documentation or evidence: • personnel laboratory specific training or certifications • BSC or CFH certificates • PRCU SOP • Laboratory SOP • Procedural examples or photographic examples. • Grant Requirements, etc.

Submitting Your Protocol for IBC Review:

☐ 1. Ensure to click the '**Save**' button often.	
☐ 2. Use the '**Validate**' button in the top left corner within your protocol to ensure all sections are complete.	
☐ 3. Click the '**Finish**' or '**Exit**' button once you are ready to submit.	 **Note:** The 'Finish' button is only available on the last page of the protocol (Supporting Documents).
☐ 4. Click '**Submit**' on the protocol's homepage.	 **Note:** The 'Submit' button is only available to the PI or PI Proxy.

Your Protocol's Homepage:

1. Add **PI Proxy**:
    a. If you have a Co-Investigator or are entering the protocol on behalf of the PI, assign that person/yourself as a PI Proxy so that they may submit any protocol modifications and receive protocol notifications along with the PI.

2. Manage Related IRB Studies and IACUC Protocols:
    a. Click **Manage Related IRB Studies** to input information about your Human Clinical Trial.
    b. Click **Manage IACUC Protocols** to input information about your Animal Use Protocol.
        i. Note: this will allow the Animal Use protocols and Safety protocols to link in Muse.

Reminders:

- Save often and use the **%** to search, especially for room numbers.
- **If you <u>cannot</u> find an agent** (biohazard, chemical, etc.), email the Biosafety Officers (BSOs) to have the agent added in Muse (kaloyd@uams.edu and dmilke@uams.edu).
- Also email the BSOs if you have any questions or need contact information for BSC Certifications.

Recommendations:

- Submit your protocol early, minimum of three weeks before IBC meeting, (**ideally 3 months before your grant deadline),** as the deadline for protocols to be approved by the Biosafety Officers for IBC review is two weeks before the monthly meeting.

    - **<u>IBC Meetings</u>: First Friday of Every Month**
        - **Example**: If the IBC meeting is Friday, April 2nd, then the protocol must be approved by the Biosafety Officer by Friday, March 19th. It is recommended to submit your protocol by Friday, March 12th in Muse so the Biosafety Officers can begin the initial review.