How to Upload Your Protocol in Muse

Institutional Biosafety Committee

IBC@uams.edu

UAMS
University of Arkansas for Medical Sciences

Presentation Overview

CONTACT INFORMATION

BIOSAFETY OVERVIEW

PROTOCOL UPDATES & HURON: MUSE

Contact Information

- James Bishop, MS
  - Director of Occupational Health & Safety
    - https://uams.edu/campusop/depts/OHS/
  - **Office**: 501-603-1288
  - **Email**: jebishop@uams.edu

- Jia Liu, PhD
  - Associate Professor, Department of Microbiology & Immunology
    - Institutional Biosafety Committee (IBC) Chair
  - **Office**: 501-686-7224
  - **Email**: jliu4@uams.edu

Biosafety Officers

Smitha Rayadurg, DVM, PhD

- **Office**: 501-686-5299
- **Email**: Vsrayadurg@uams.edu

Kate Loyd, BS

- **Office**: 501-296-1083
- **Email**: Kaloyd@uams.edu

Biosafety Overview

Occupational Health & Safety

UAMS OH&S Biological Safety Division

Biological Safety Division

http://www.uams.edu/campusop/depts/ohs/divisions.aspx?listid=bio

Institutional Biosafety Committee (IBC)

http://www.uams.edu/campusop/depts/ohs/BioSafety_Cmte.aspx

Stakeholders Involved

IACUC, IRB, Lab staff, PI's, Facilities, Maintenance, & Contractors

UAMS Biosafety Overview

The UAMS Biosafety Program is administered by the **Biological Safety Division** of the Occupational Health & Safety Department. Oversight of the program is provided by the Institutional Biosafety Committee (IBC).

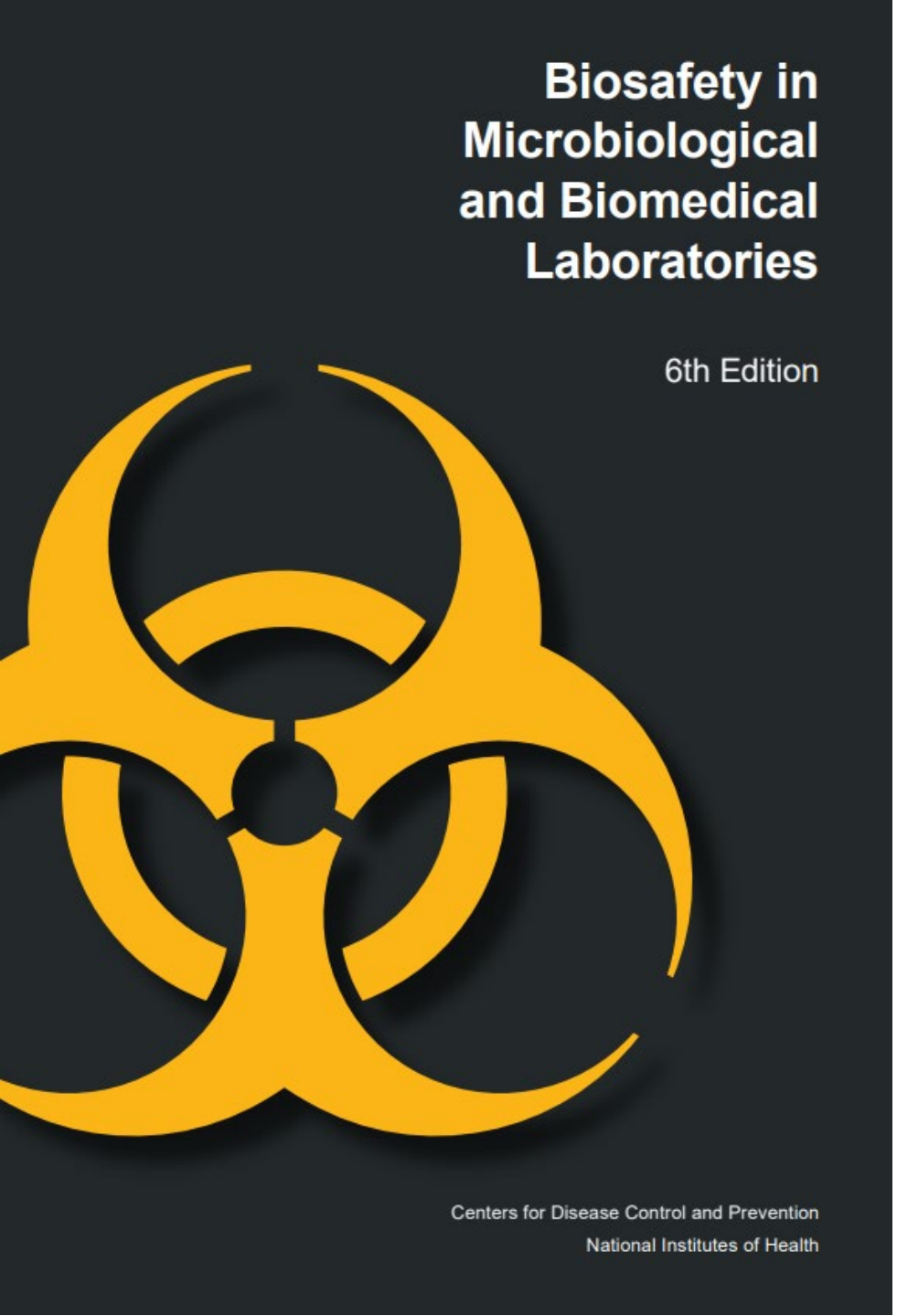
The purpose of the UAMS Biosafety Program is to minimize the health risk to faculty, staff, students, and the public by identifying, evaluating, and controlling potential exposure to biohazardous materials used in research and teaching activities at UAMS.

UAMS Biosafety Policies & Procedures

UAMS Biosafety Manual
UAMS Laboratory Safety Manual
Laboratory Inspection Checklists for BSL1, BSL2 & BSL3
Laboratory Close-out Checklists
Incident Reporting (form on website)
Biohazard Waste Disposal Form
Shipping & Transport SOP
Bloodborne Pathogen Notice
Exposure Control Plan
Respiratory Protection Program
UAMS BSL3 Manual & Policies

Campus Policies & Manuals

- Policy 11.4.08:
  - *All UAMS employees, students, volunteers, and visitors will follow the UAMS Laboratory Safety Manual developed by the Department of Occupational Health & Safety.*
- **Primary Responsibility belongs to Principal Investigator (PI)**:
  - Must ensure safe conduct and conditions in the laboratory or research area.
- Laboratory Safety & Biosafety Manuals on OH&S website:
  - https://uams.edu/campusop/depts/OHS/
  - Or Policies & Procedures in UAMS Compliance 360



Biohazards

- **Biohazardous materials include infectious or etiologic agents of humans, animals and plants.**
- Biohazardous agents may include but are not limited to:
  - Certain bacteria, fungi, viruses, rickettsiae, spirochetes, protozoa, & parasites
  - Recombinant or synthetic nucleic acid molecules
  - Viral agents and prions
  - Human blood & body fluids
  - Cultured human or animal cell lines and the potentially infectious agents these cells may contain
  - Nonhuman primate cells & tissues
  - Biological toxins
  - Listed Select Agents & Toxins (exempt & non-exempt quantities)
  - Zoonotic agents
  - Arthropods
  - Other infectious agents as outlined in laws, regulations, or guidelines.

Biosafety Guidance & Regulations

Biosafety in Microbiological & Biomedical Laboratories BMBL 6th ed
OSHA Bloodborne Pathogen Standard
NIH Recombinant & Synthetic Nucleic Acid Guidelines (2019)
Interim Biosafety Guidance from NIH & CDC
CDC Select Agent Regulations
DOT/IATA Shipping of Infectious Substances
Chemical Hygiene Plan
Material Transfer Agreements
Import Permits
Dual Use Research of Concern
Export Control

National Institute of Health (NIH): Oversight of Research

- Compliance with NIH Guidelines is required to receive NIH funding.
- NIH Guidelines are applicable to all research for **recombinant or synthetic nucleic acid molecule research**:
  - Regardless of the funding source of an individual projects.
- The NIH Guidelines establish different levels of review and approval based on the nature of the activity.

NIH National Institutes of Health
Turning Discovery Into Health

The NIH Guidelines

Section III-A: Approval from the NIH Director and the IBC before initiation of the research.

Section III-B: Approval from NIH OSP and the IBC before initiation of the research.

Section III-C: Approval from the IBC before initiation of human gene transfer research.

Section III-D: Approval from the IBC prior to initiation of the research.

- Most UAMS Research is Section III-D

Section III-E: Notification of the IBC simultaneous with initiation of the research with subsequent IBC review and approval.

Animal Biosafety Levels at UAMS

Work involving laboratory animals – IBC approval is a prerequisite for obtaining approval from the IACUC

UAMS DLAM & IACUC Policies & Procedures

DLAM Director: Christy Simecka, DVM

IACUC Chair: Jerry Ware, DVM

John Lowery, DVM

Dan Eldridge, DVM

Four biosafety levels for work with vertebrate animals exposed to agents which may infect humans.

Animal Biosafety Levels (ABSL 1-4).

UAMS Select Agent Program

- Biological agents and toxins that could pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products.
  - Select Agents & Toxins List
- For registration with CDC to work with Select Agents, please consult:
  - UAMS IBC
  - Responsible Official, James Bishop
  - Alternate Responsible Official, Kate Loyd

Protocol Amendment Approval

Administrative Approval:

Does **not** change risk status of your IBC application:

- Adding/deleting personnel
- Changing location of your work
- Adding other species of hazardous agents already approved.

IBC Approval:

Changes the risk status of your IBC application:

- Change/Adding in Procedure
- Change/Adding Agents
- New Hazards
- Potential biological or chemical exposure to DLAM staff

Training Responsibilities of the PI

Complete UAMS mandatory training modules prior to receiving the IBC approval.

Provide laboratory specific training to staff on hazard risks, SOPs, PPE, Biosafety Cabinet Use, Chemical Fume Hood Use, Occupational Health, & Emergency Services.

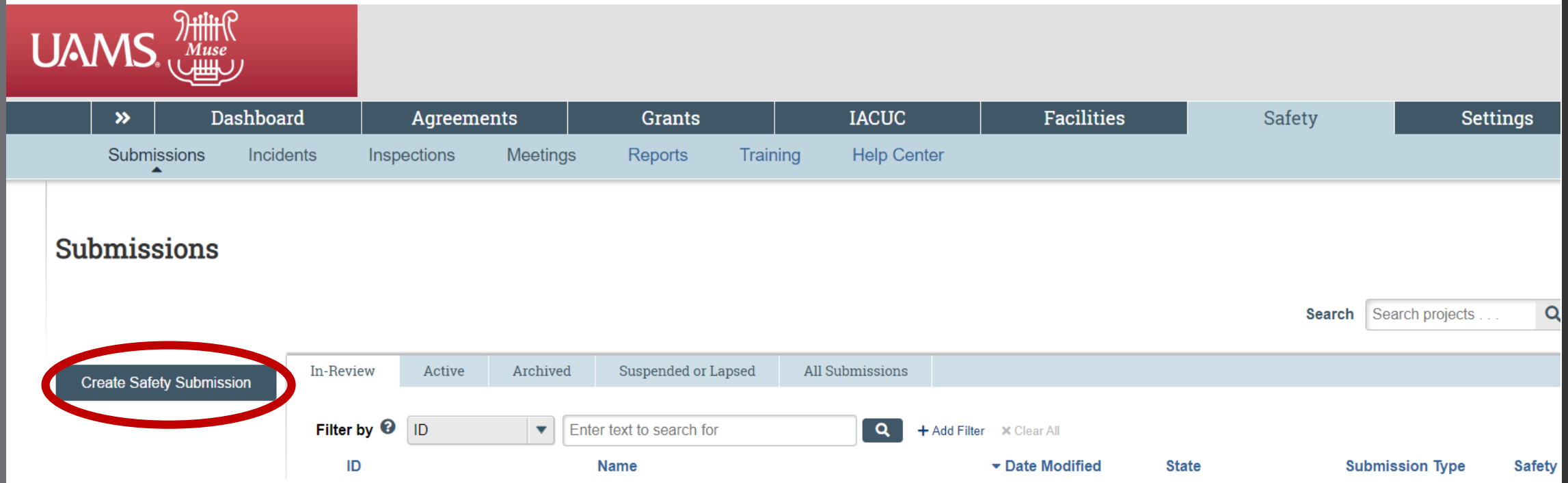
Training should be **documented** & understood:

-Using MyCompass or uploading Lab Specific Trainings in Supporting Documents.

How to Upload Your Protocol in Muse

https://muse.uams.edu

Click **Create Safety Submission** to begin entering your protocol in Muse in the Safety Section.



Getting Started in Muse

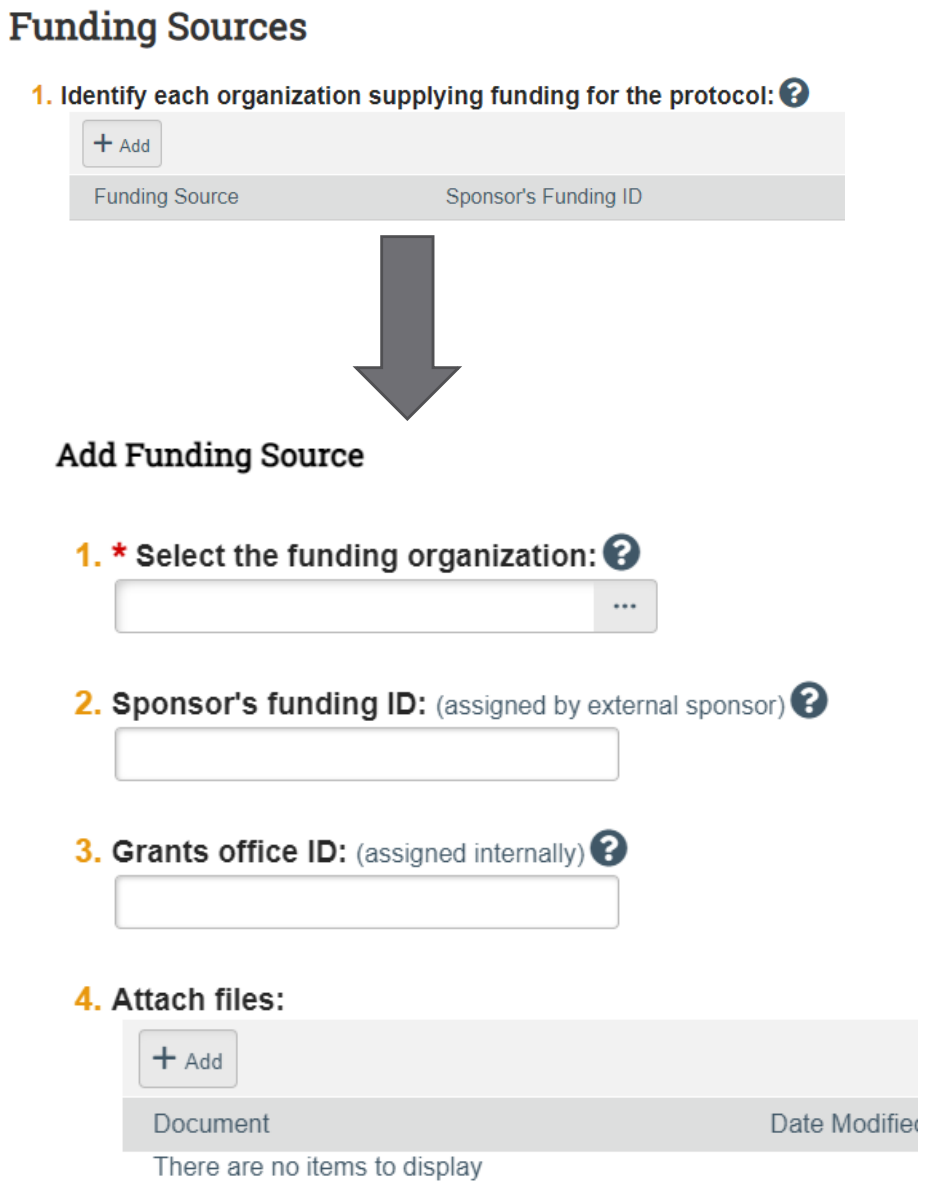
Basic Information

- Select **Safety** in step One
- Input the **Protocol Title** & Short Title
- Describe the **Summary of Research:**
  - Describe **Biosafety** aspects of each proposed project:
    - Pathogens
    - Recombinant DNA
    - Eukaryotic cells
    - Species & Strain of Lab Animals
    - Hazardous Chemicals
- Safety Review **Type** (Biosafety & Radiation)
- **Principal Investigator** Information
- Research Location: select appropriate campus

Protocol Team Members

- Identify each member of staff:
  - Laboratory & Administrative
- Team Member Training:
  - Loads from MyCompass
    - Basic Lab Safety Training
    - Lab Specific Trainings

Course	Category	Source	Stage	Stage Number	Completion Date	Expiration Date
Research Lab Personnel Medical Screening	None	MyCompass			9/13/2021	
Animal Research Requirements Training Course	None	MyCompass			9/20/2021	
CO Bloodborne Pathogens	None	MyCompass			8/26/2021	
CO Chemical / Laboratory Safety Refresher Training	None	MyCompass			8/26/2021	
CO Basics of Biosafety Training	None	MyCompass			8/26/2021	
CO DOT-IATA Shipping Infectious Substances	None	MyCompass			8/26/2021	8/26/2023
CO NIH Guidelines for Recombinant DNA Research	None	MyCompass			8/26/2021	



Funding Sources

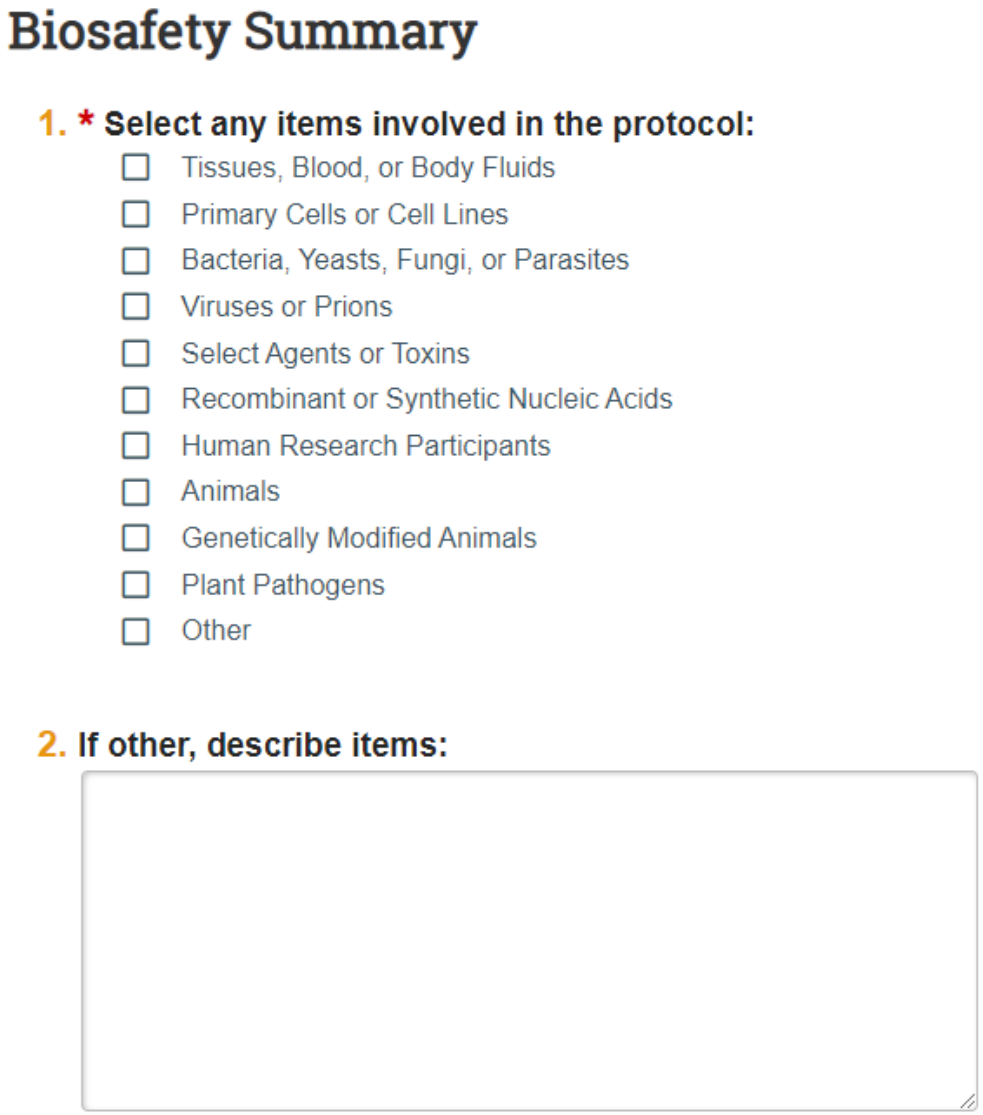
Select +Add to add **Funding Organization**

Provide detailed funding information

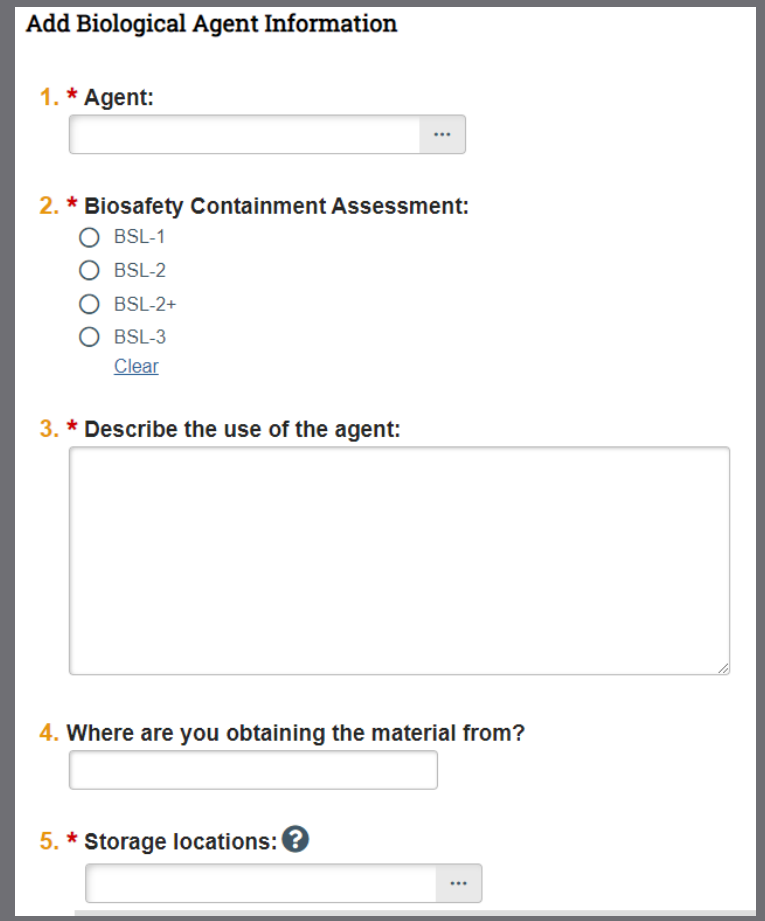
Can upload any relevant documents

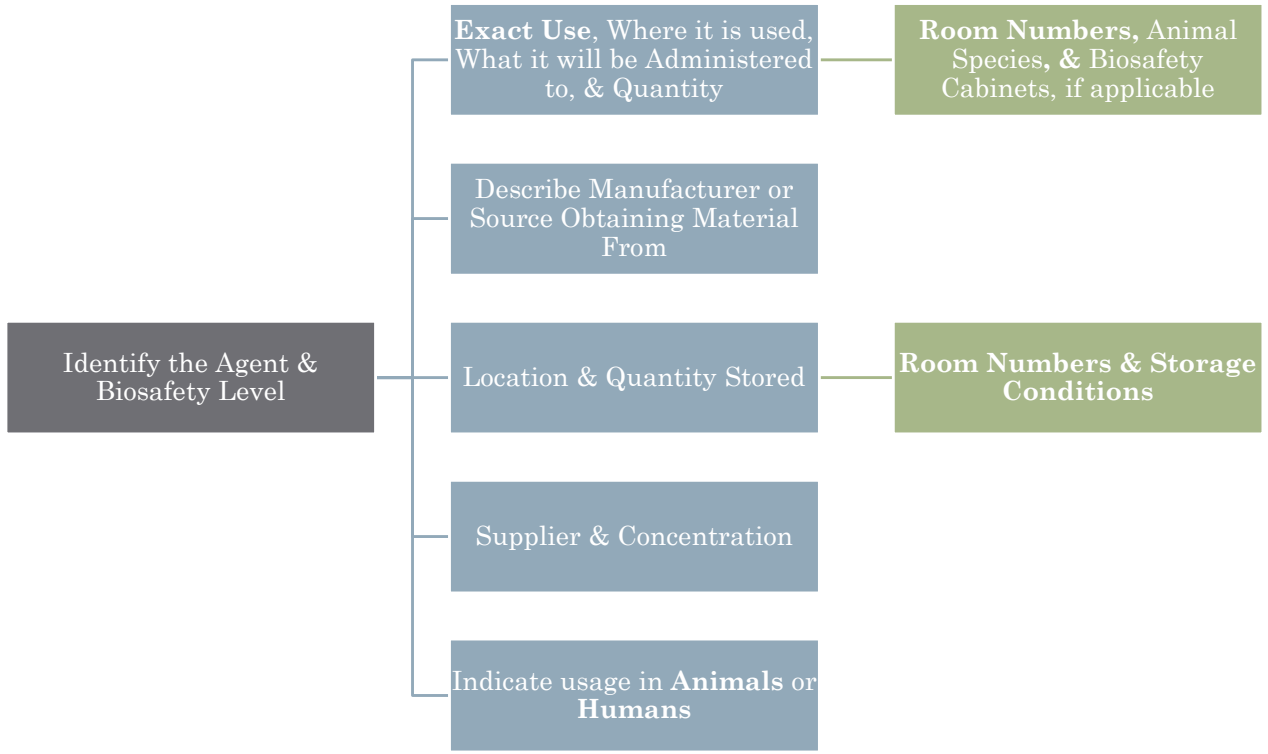
Biosafety Summary

- Select **All** Agents that will be used in your protocol:
  - Each Agent type will be described in their own section.
  - Agent specific pages will be added in the smart form.
- Ensure to describe **Other**, if selected



Agents, Toxins, & Microorganisms

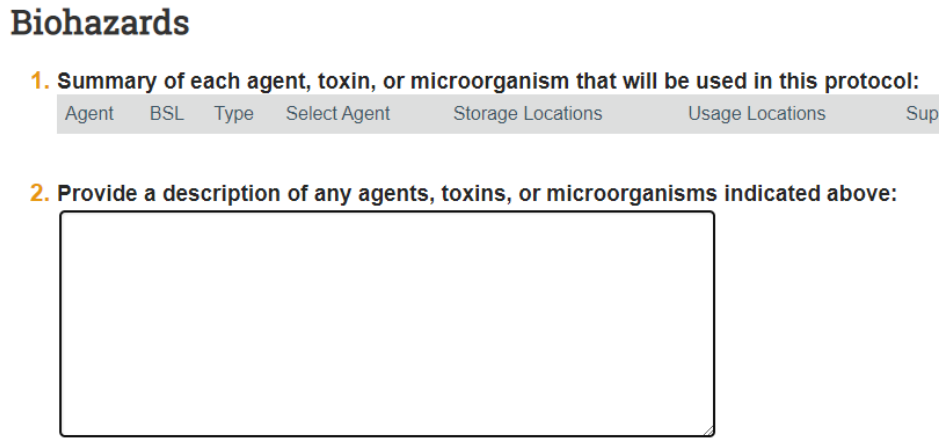




- Remember to note **Biosafety Cabinet** Locations (Room #) and Certification Dates.
- Can upload more info in **Supporting Documents.**

Agents, Toxins, & Microorganisms: **Biohazards**

- Describe the **biohazards** associated with each Agent Toxin, or Microorganism Identified.
- Identify any other important information about each Biohazard:
  - Necessary PPE
  - Biosafety Cabinet Use
  - If Work Related Training is needed



Biohazards

1. **Summary of each agent, toxin, or microorganism that will be used in this protocol:**

Agent	BSL	Type	Select Agent	Storage Locations	Usage Locations	Sup

2. **Provide a description of any agents, toxins, or microorganisms indicated above:**

Recombinant or Synthetic Nucleic Acids Usage

1. * Does research with recombinant or synthetic nucleic acids involve the use of: (select all that apply)

☐	Section III-A	Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval Before Initiation
☐	Section III-B	Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation
☐	Section III-C	Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation
☐	Section III-D	Experiments that Require Institutional Biosafety Committee Approval Before Initiation
☑	Section III-D-1-a	Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment
☑	Section III-D-3	Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
☐	Section III-E	Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation
☐	Section III-F	Exempt Experiments
☐		A deliberate release of genetically-modified (insertion of recombinant or synthetic nucleic acids) plants or animals into the environment
☐		None of these apply

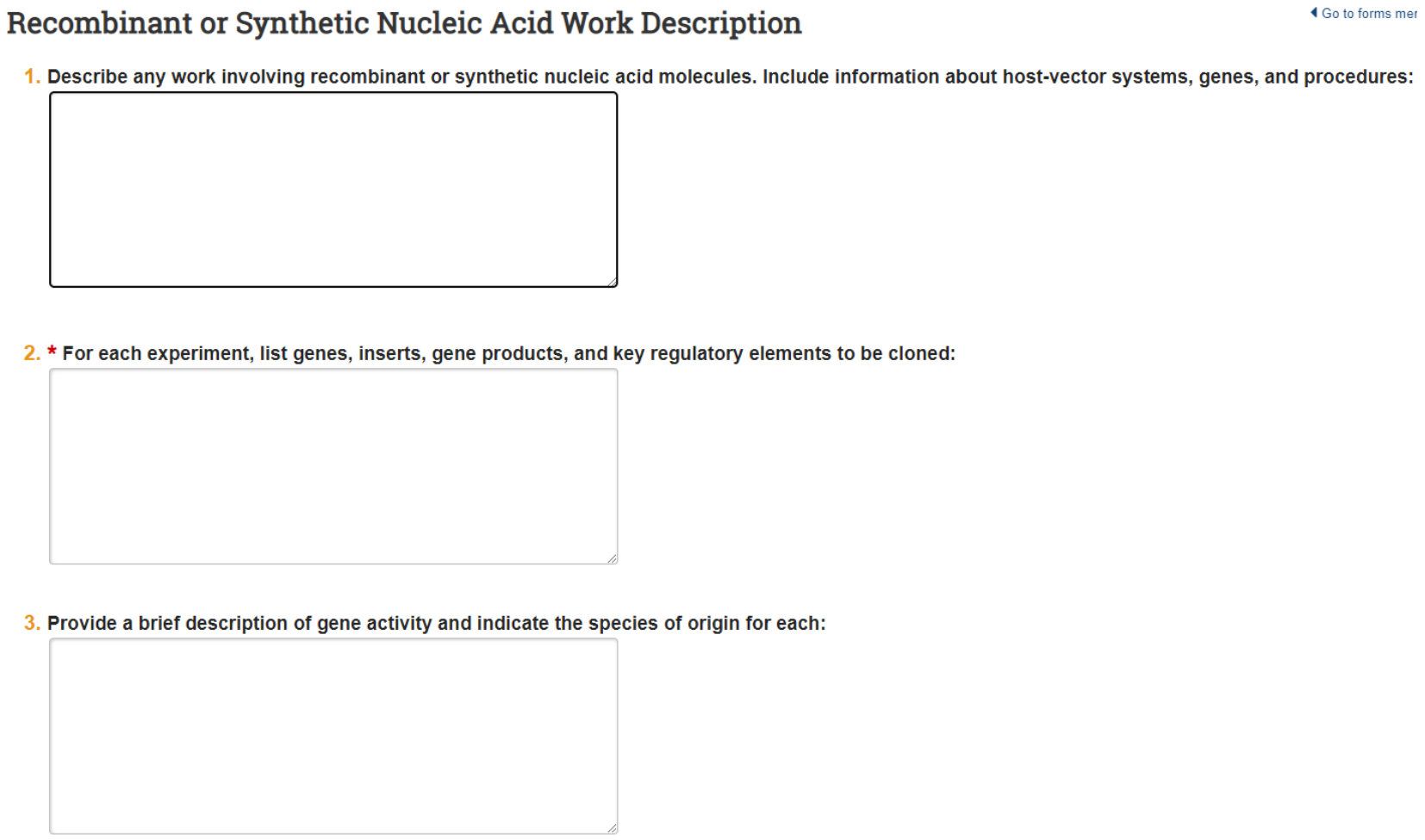
2. If none of these apply, describe:

Recombinant or Synthetic Nucleic Acids Usage

- Select all that Apply
- Can use dropdown arrows for more options
- See NIH Guidelines for more information

Recombinant or Synthetic Nucleic Acid Work Description

- Describe in detail the genes, procedures, and vectors involved
- More information is best:
  - Can type in Word, then copy & paste
  - Can use bullet points



Recombinant or Synthetic Nucleic Acid Work Description

Go to forms mer

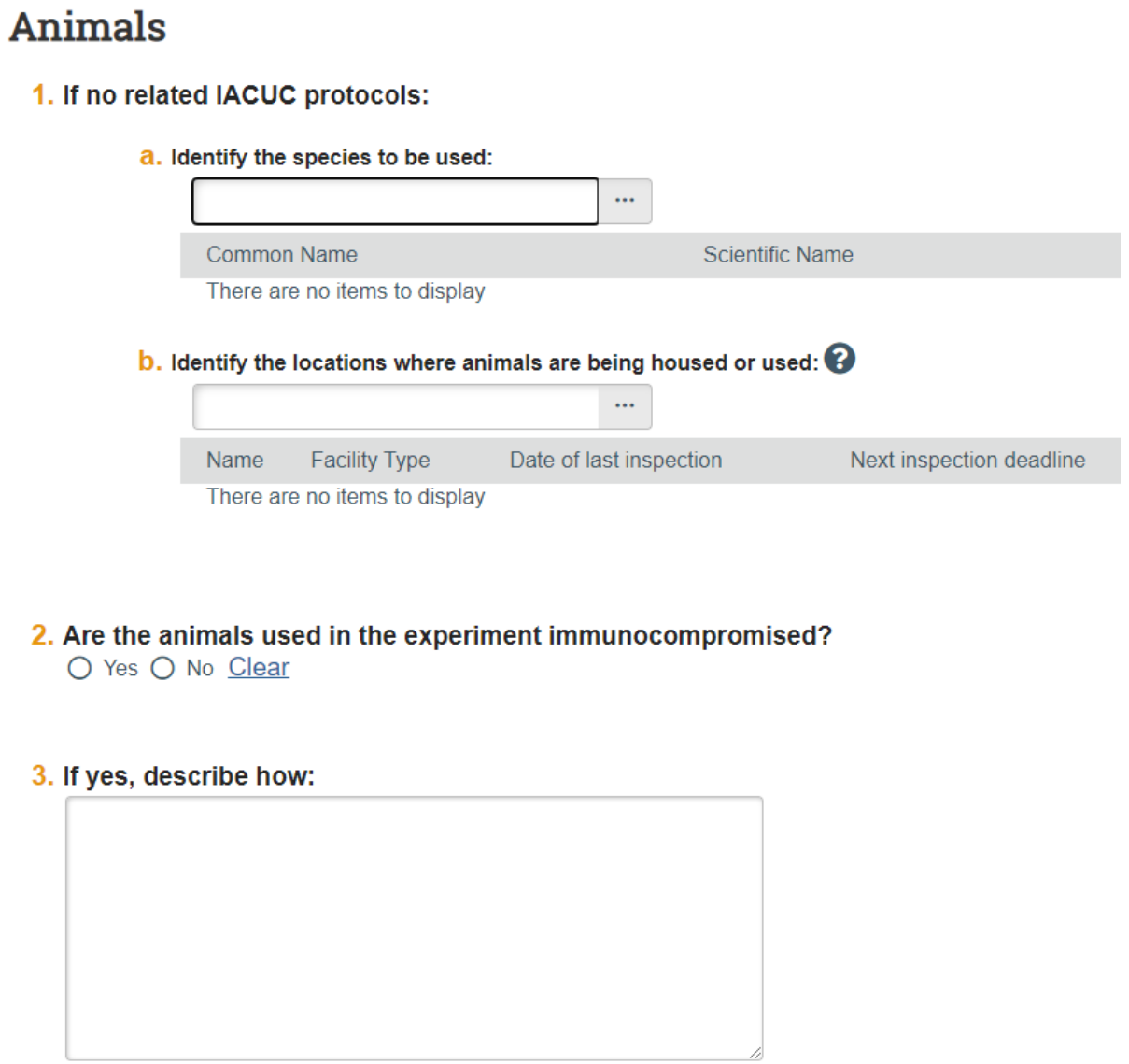
1. Describe any work involving recombinant or synthetic nucleic acid molecules. Include information about host-vector systems, genes, and procedures:

2. * For each experiment, list genes, inserts, gene products, and key regulatory elements to be cloned:

3. Provide a brief description of gene activity and indicate the species of origin for each:

Animals

- Animals and Genetically Modified Animals section
  - Generated if selected in Biosafety Summary
- List animal species and hazards associated
- Indicate AUP# if known
- Indicated Room Number of Housing Location



Risk Group & Containment Practices

- Select appropriate Risk Group and Biosafety Containment Level for your research:
  - Most research at UAMS is BSL-2, BL-2, and/or ABSL-2

Risk Group and Containment Practices

Go to forms menu | Print | Help

If you are unsure about the risk group designation of an agent and/or material please refer to the NIH Guidelines Appendix B.

1. What is the highest risk group level of the biological agents and materials you will use in the proposed research?

- ○ RG-1
- ○ RG-2
- ○ RG-3
- ○ RG-4

Clear

2. What are the highest biosafety containment practices required for the research activities covered by this protocol? (If you are unsure about the required containment practices for your research activities refer to the BMBL or NIH links in each category below.)

BMBL:

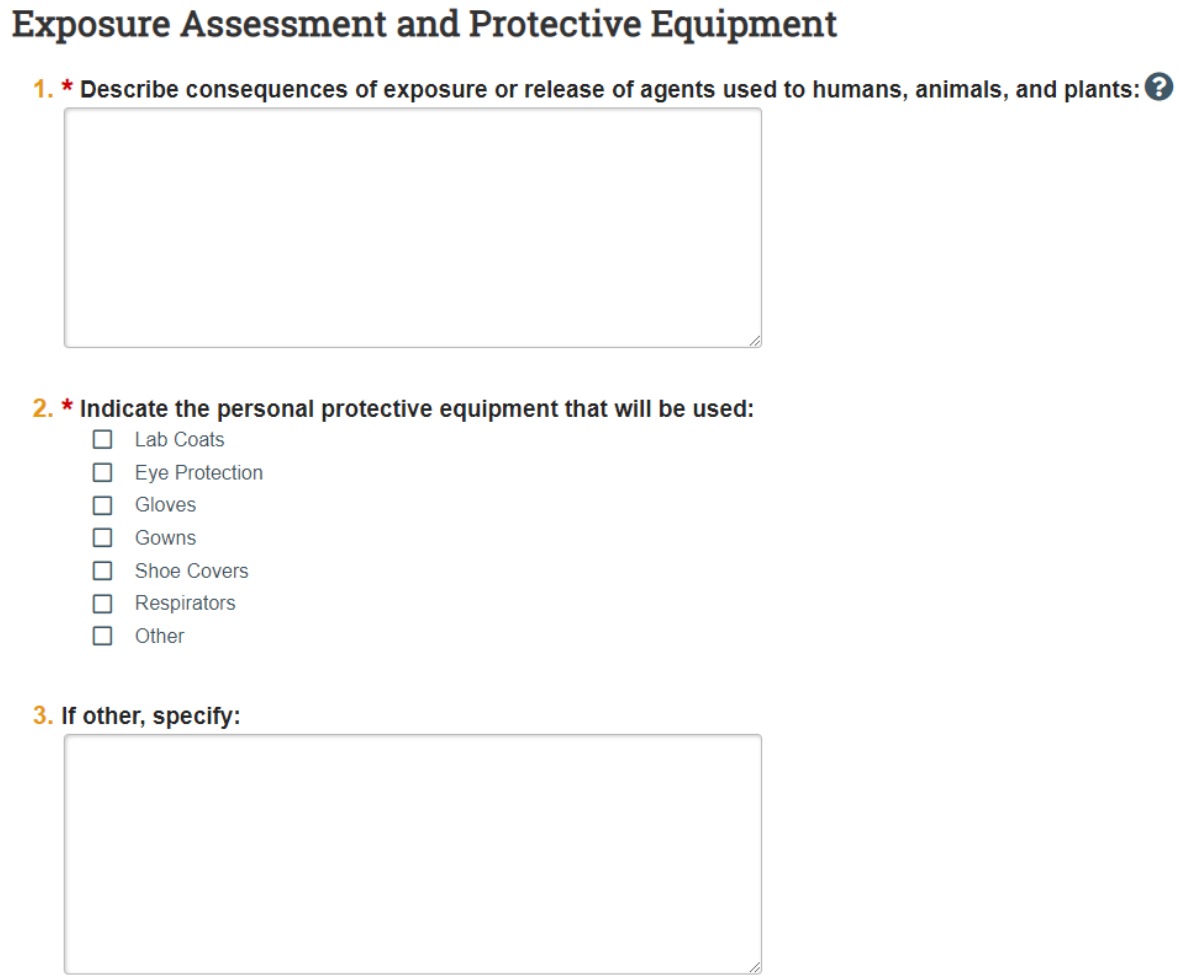
Biological Research Standards	Biological Research Involving Animals	Biological Research Involving Arthropods
○ BSL-1	○ ABSL-1	○ ACL-1
○ BSL-2	○ ABSL-2	○ ACL-2
○ BSL-2+	○ ABSL-2+	○ ACL-3
○ BSL-3	○ ABSL-3	Clear
Clear	Clear	

NIH Guidelines *rDNA* or synthetic nucleic acids:

Physical Containment	Research Involving Animals	Research Involving Plants	Large-scale Uses of Organisms
○ BL-1	○ BL1-N	○ BL1-P	○ BL1-LG
○ BL-2	○ BL2-N	○ BL2-P	○ BL2-LG
○ BL-3	○ BL3-N	○ BL3-P	○ BL3-LG
Clear	Clear	Clear	Clear

Exposure Assessment and Protective Equipment

- Identify Safety Hazards & their Consequences:
  - Schedule an **OH&S Consult** on our website, if needed
- Consequences of Exposure:
  - Skin, needle-stick, eyes, mucous membranes, respiratory exposure, etc.
    - Notify PI & UAMS Biosafety Officer
    - Go to Student & Employee Health or Emergency Department, if needed
    - Completed **Incident Form** on website
- Identity Consequences of release of exotic agents, animals, & plants:
  - How release will be prevented & agent or organism contained
- Select PPE used to mitigate risk



Exposure Assessment and Protective Equipment

1. * **Describe consequences of exposure or release of agents used to humans, animals, and plants:**

2. * **Indicate the personal protective equipment that will be used:**
   - ☐ Lab Coats
   - ☐ Eye Protection
   - ☐ Gloves
   - ☐ Gowns
   - ☐ Shoe Covers
   - ☐ Respirators
   - ☐ Other

3. **If other, specify:**

Dual Use Research of Concern

1. * **Dual use experiment categories used in this research:** (select all that apply)
   - ☐ Enhances the harmful consequences of the agent or toxin
   - ☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
   - ☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions, or facilitates the agent or toxin's ability to evade detection methodologies
   - ☐ Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
   - ☐ Alters the host range or tropism of the agent or toxin
   - ☐ Enhances the susceptibility of a host population to the agent or toxin
   - ☐ Generates or reconstitutes an eradicated or extinct agent or toxin
   - ☐ None of the above

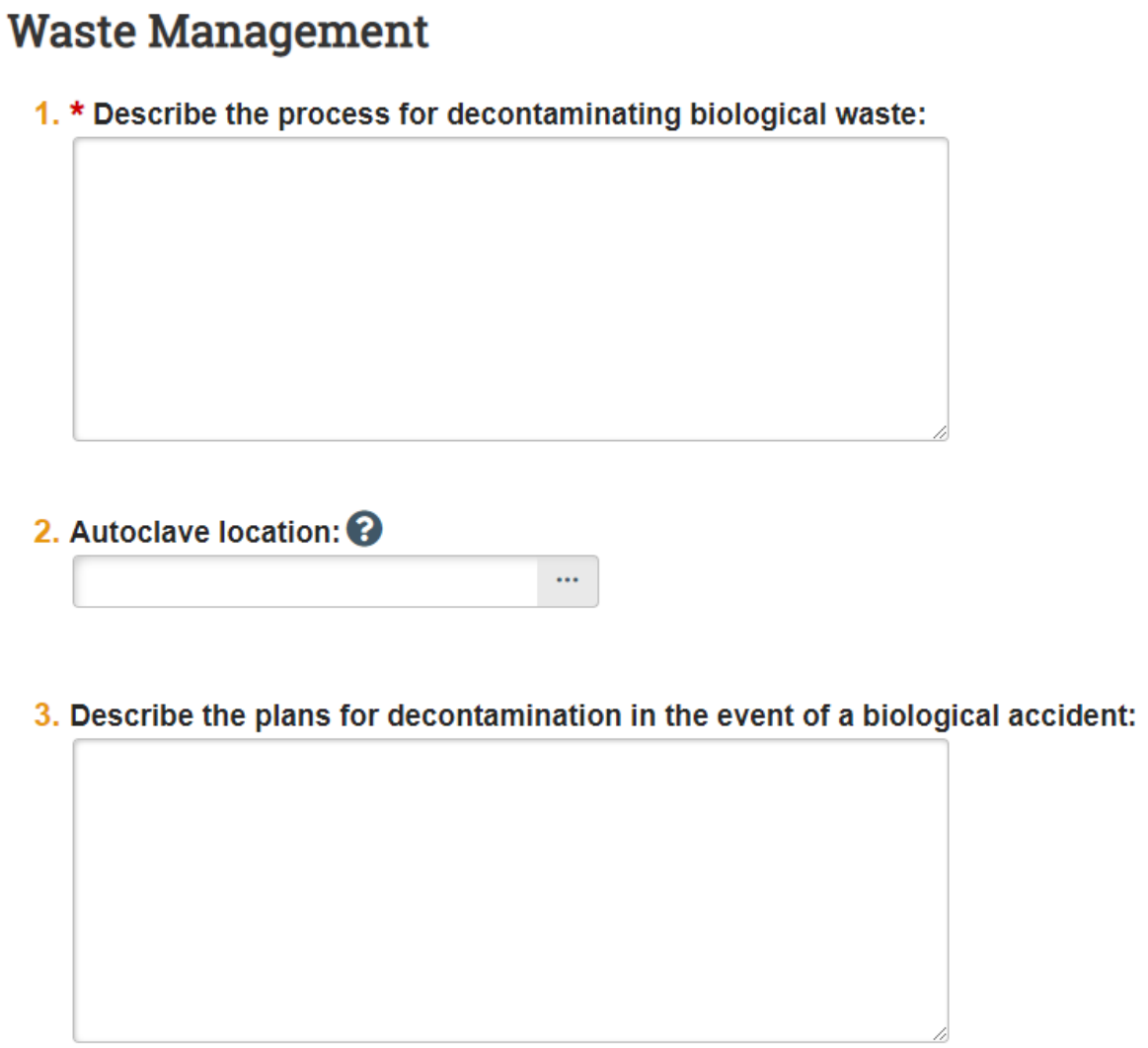
Note: If you checked any dual use categories above and use agents or toxins in the research, the protocol is likely to be dual use research of concern.

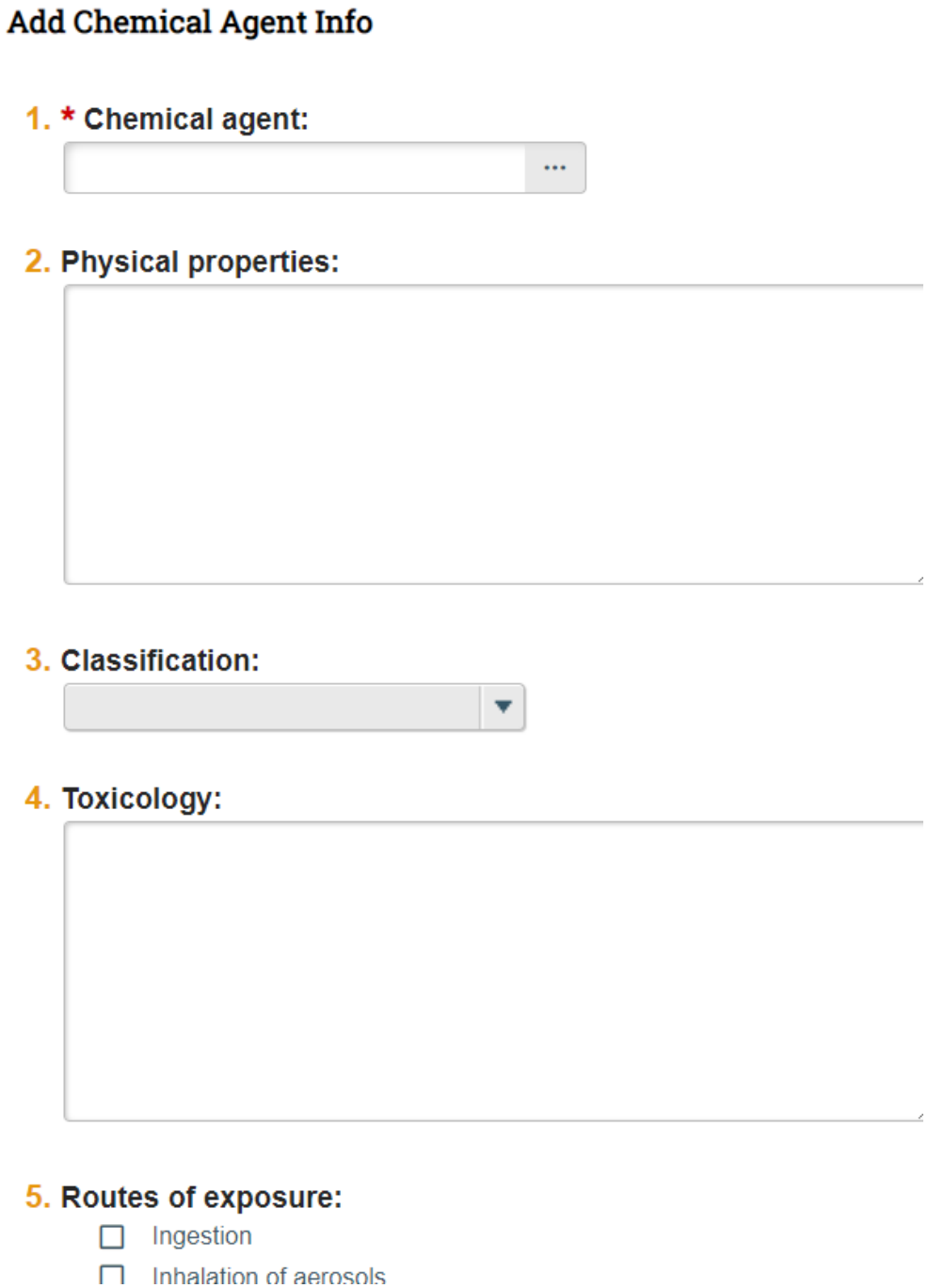
2. * **Explain why you believe this protocol is or is not dual use research of concern:**

Dual Use Research of Concern

Waste Management

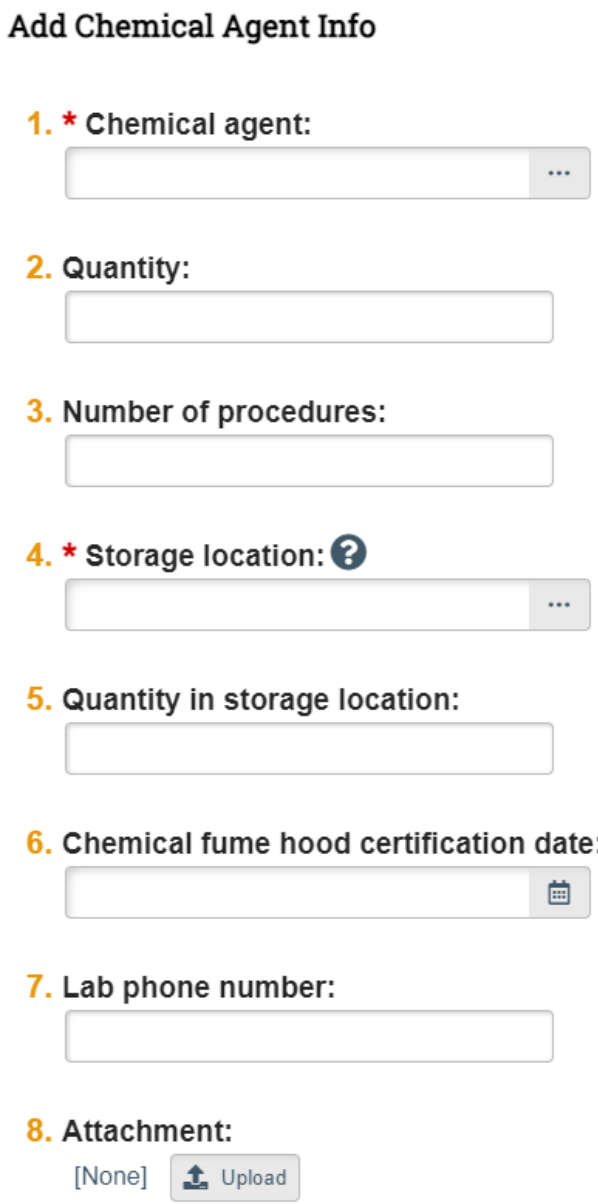
- For **each** Biological Agent indicate disposal & disinfection process:
  - For the agent, equipment, & BSC used
  - Animal Bedding
  - Glass & Plastic Ware
- Indicate Disinfectant Used & Contact Time:
  - Example: 10% Bleach for 30 minutes
  - Example: 70% Alcohol until dried
- Indicate Autoclave Use:
  - Describe Cycle Time & Temperature
- Describe Decontamination Plans for Biological Accidents:
  - Large & Small Spills
  - See Biosafety Manual, if needed





Chemical Hygiene

- List **All** Hazardous Chemicals, Drugs, & Reagents used & indicate:
  - Physical Properties
  - Classification
  - Toxicology:
    - Carcinogen, Mutagen, Teratogen, Toxin, etc.
  - Routes of Exposure, Limits, & Monitoring Requirements
- Recommend using **Manufacturer's SDS**

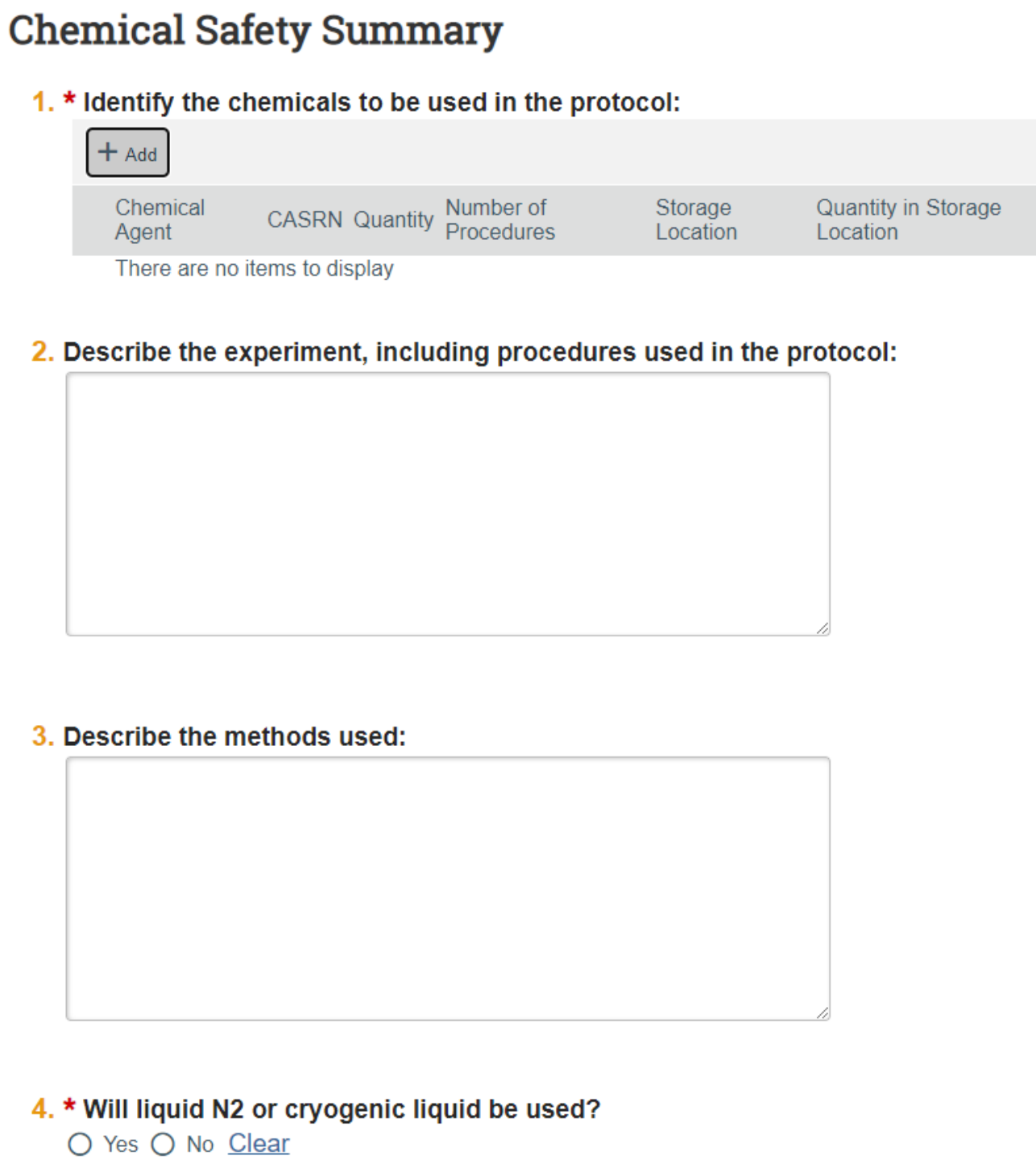


Chemical Safety Summary

- Indicate Chemical Fume Hood Certificate Date, if applicable
- Recommend uploading Manufacturer's SDS in Attachments

Chemical Safety Summary

- For all chemicals identified, describe their use:
  - Chemical Fume Hood Use & Location
    - Where and how prepared
  - Chemical Use (administered to animals, etc.)
    - Highest dose
    - Regime for Dosing
  - Amount Used and Generated
- Method & Location of administration
  - Biosafety Cabinet Use
- Liquid Nitrogen and/or Cryogenic Use



Chemical Safety Summary

1. * **Identify the chemicals to be used in the protocol:**

+ Add

Chemical Agent	CASRN	Quantity	Number of Procedures	Storage Location	Quantity in Storage Location

There are no items to display

2. **Describe the experiment, including procedures used in the protocol:**

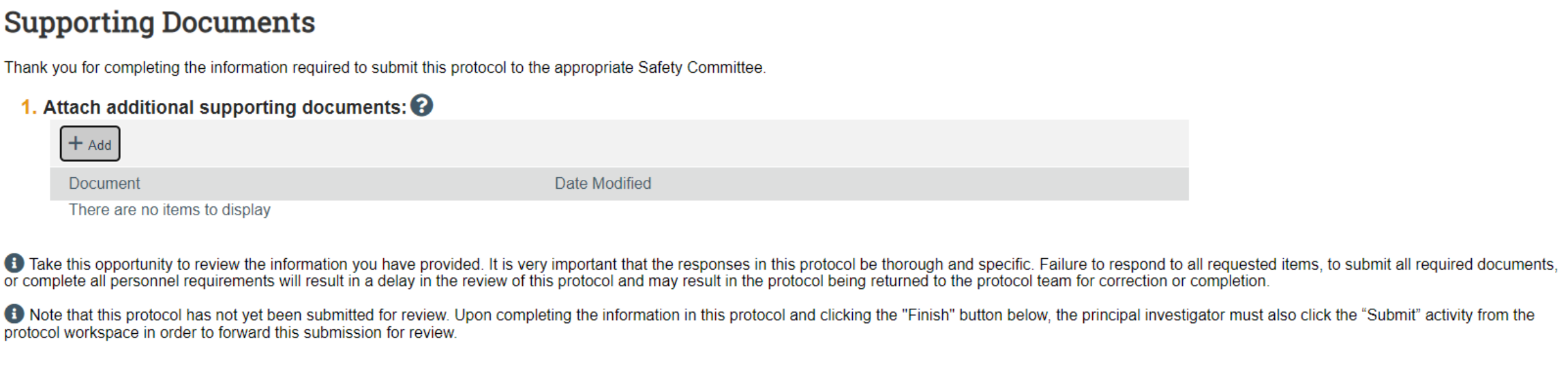
3. **Describe the methods used:**

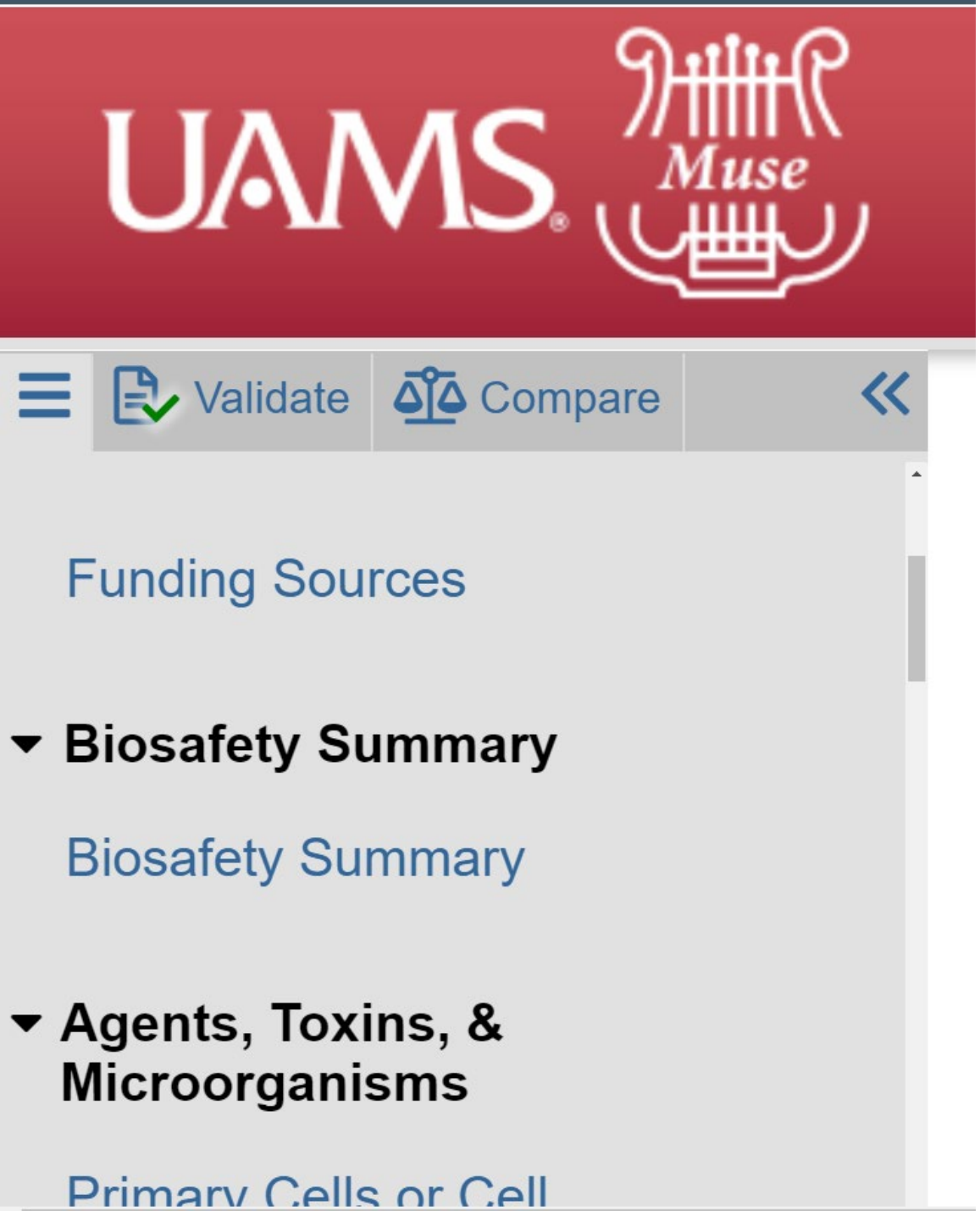
4. * **Will liquid N2 or cryogenic liquid be used?**

○ Yes ○ No Clear

Supporting Documents

- Upload any Data, Protocols, SDS, Validations, or Articles that supports your protocol.
- Upload any **USDA permits** or applicable shipping documents.
- Upload any Lab Specific **Training Documents** not listed in MyCompass.
- Upload originally **approved protocol**, if you already have approval.



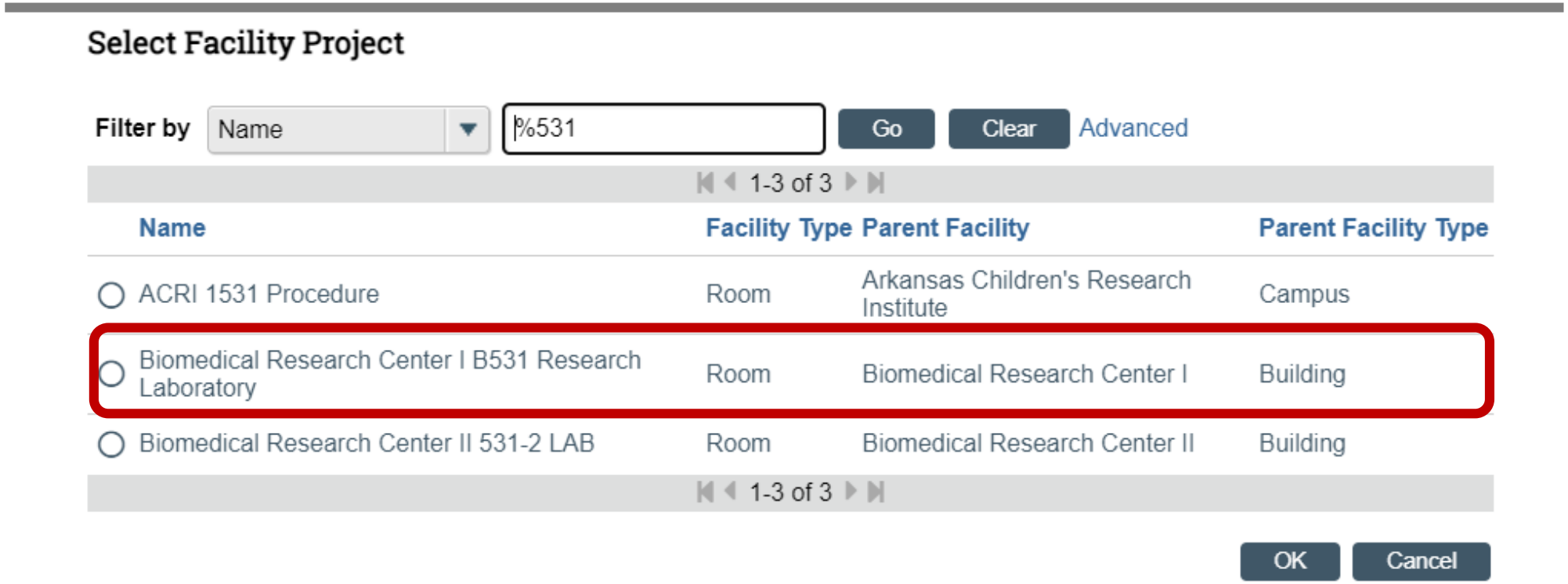


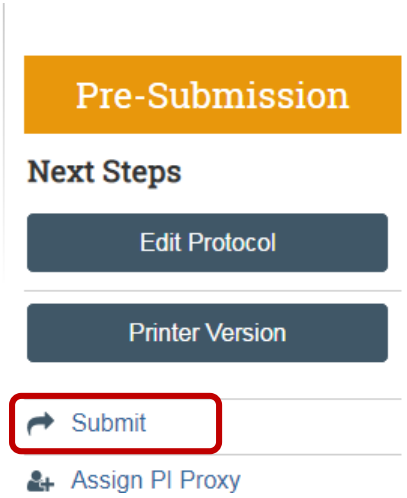
Muse Tips & Tricks

- Use the **Validate** Button to check if you missed any fields.
- Use the **Compare** Button review your entire working protocol.
- Remember, the more information the better and contact us with any questions!

Searching in Muse

- Use the % symbol before a search field to Search All for the item.
- **Example**: If you are looking for Biomed I Room B531, you can search **%531** and hit **Go**.
  - Select the correct room number and hit **OK**
    - *Hint*: ensure **Filter by** is correct.





Huron: Muse Overview

- Contact IBC Chair or Biological Safety Officers with any questions or suggestions for the Muse Program
- Ensure to click Save as you are working
- Click **Submit** to submit your protocol & begin the IBC review process.

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.

Note: Depending upon your agents, different sections will become available. Some sections below may not be applicable to your protocol and can be left blank or removed. 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	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.
☐ 4. Select Appropriate Safety Review	Select Biosafety. Only select Radiation Safety if you are working solely with radiation and no other hazards.
☐ 5. Principal Investigator	Type and select the Principal investigator.
☐ 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.

Muse Protocol Checklist

- Use the **Muse Protocol Checklist** to assist you with entering your protocol.
- The Checklist gives detailed instructions for each section:
  - Use the **Navigation** pane to go to each section.
- The Checklist also gives instructions on how to input your old paper protocol
- Also gives examples and example statements to use.