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Basic Information

1. * **Select admin office:** Safety

2. * **Title of protocol:**
   Example Muse Protocol

3. * **Short title:**
   Example Muse Protocol

4. * **Summary of research:**
   Example Muse Protocol

   In our research, we will examine the emerging disease, Morbus Mysterium, that affects the immune system and is caused by the Mysteria Virus.

   The protocol will encompass a human gene therapy drug trial and an animal model to examine the mechanism of disease, examine a new gene therapy, and identify best practice dosage for the traditional antiviral treatment.

   1) Gene Therapy: Drug X, is an AAV vector gene therapy that will be administered intravenously to patients enrolled in the clinical trial in the Mystery Disease Clinic located in the UAMS Cancer Institute. This drug will be prepared by clinical pharmacy staff and administered by clinical staff that have all undergone NIH Recombinant DNA training. Patient samples of blood and urine will be collected at 72 hours, 1 week, and 1 month post drug administration. These human samples will be taken to the laboratory located at Cancer Institute for biochemical analysis and quantitative assays for viral shedding.

   2) Animal model: Example mice strain will be used for their overexpression of the Example protein, which is found to play a role in the Mysteria Virus propagation. The mice will be inoculated with the Mysteria Virus in a BSC via subcutaneous injection. The mice will undergo traditional treatment with antiviral agent Chemical Z, however, high doses cause cardiac toxicity. This will be administered in varying dosages to see if an improved dosing model can be found. See the IACUC animal use protocol for the dosage schedule (IPROTO202000000123).

   All sample manipulation and drug manipulation will be performed in full PPE within a Biosafety Cabinet (BSC). All drug administration will be performed in full PPE. Animal handing will be performed in full PPE and a BSC in accordance with DLAM guidance.

   Note: Please ensure that the appropriate sections are included for your experiments and the hazards handled. In the example above, the following 'Biosafety Summary' sections should be selected and completed:
   -Tissues, Blood, or Body Fluids
   -Viruses or Prions
   -Recombinant or Synthetic Nucleic Acids
   -Human Research Participants
   -Animals
   -Other (#2 Chemicals)

   Example Muse Protocol

5. * **Select appropriate safety review:** Biosafety

6. * Principal investigator:

Katherine Loyd

7. Research Locations:

UAMS

Protocol Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

Name	Roles	Additional Roles	Involved With Procedures	E-Mail	Phone
Donka Milke	Co-Investigator		yes	DMILKE@UAMS.EDU	5016865299

2. Team member training:

Filter by First Name Enter text to search

Clear All

Filter by First Name Enter text to search

Add Filter Clear All

One or more data sources failed to load. Contact your system administrator for assistance.

First Name	Last Name	Training

First Name	Last Name	Training

3. External team member information:

Document	Date Modified

There are no items to display

Example Muse Protocol

View: SF: Funding Sources (not integrated with Grants)

Funding Sources

1. Identify each organization supplying funding for the protocol:

Funding Source	Sponsor's Funding ID	Grants Office ID	Documents
University of Arkansas for Medical Sciences	Occupational Health & Safety	Biosafety Office	

Example Muse Protocol View: SF: Biosafety Summary

Biosafety Summary

1. * Select any items involved in the protocol:

Tissues, Blood, or Body Fluids
Viruses or Prions
Recombinant or Synthetic Nucleic Acids
Human Research Participants
Animals
Other

2. If other, describe items:

Chemicals

Tissues, Blood, or Body Fluids

1. * List Agent, type, and source of all tissues, blood, and body fluids:

	Agent	Biocontainment Level	Source	Type	Used in Animals
View	Human Blood	BSL-2	Human Donor	Blood	no
View	Urine	BSL-2	Human Donor	Body Fluid	no

2. Describe any tissues transplanted between species:

N/A

3. Describe the quantity of tissues and volumes of fluids to be used:

1-3 mL of blood and 10 mL of urine per patient from approximately 20 patients.

Example Muse Protocol

View: Create/Edit Tissues, Blood, or Body Fluids View

1. * Agent:
Human Blood

2. * Biosafety Containment Assessment: BSL-2

3. * Describe the use of the agent:
Human blood will be collected from patients in the clinical area that have the virus. The blood will be centrifuged, processed using a BSC and PPE, and undergo biochemical analysis.

4. Where are you obtaining the material from?
Human Donor

5. * Storage locations:

Facility	Building	Usage
Cancer Institute 4043 PROCEDURE	Cancer Institute	

6. * Usage locations:

Facility	Building	Usage
Cancer Institute 3010 Lab	Cancer Institute	

7. Supplier:
Human Donor

8. Quantity:
approximately 1-3 mL from each patient

9. Personnel that will be handling the material:
Donka Milke

10. Experimental concentration:
N/A

11. Is agent used in animals?
○ Yes ● **No**

12. Is agent used in humans?
○ Yes ● **No**

13. Is agent recombinant or synthetic?
○ Yes ● **No**

Example Muse Protocol View: Create/Edit View for Agents

1. **Name:**
   Human Blood

2. **Agent type:**
   Blood

3. **Classification:**
   Human

4. **Is select agent:**
   ○ Yes ● **No**

5. **Risk group:** RG-2

6. **Usage Order:**

Example Muse Protocol

View: Create/Edit Tissues, Blood, or Body Fluids View

1. * **Agent:**
   Urine

2. * **Biosafety Containment Assessment:** BSL-2

3. * **Describe the use of the agent:**
   Human urine will be collected from patients in the clinical setting and undergo urinalysis and urine pregnancy test in the research laboratory.

4. **Where are you obtaining the material from?**
   Human Donor

5. * **Storage locations:**

Facility	Building	Usage
Cancer Institute 4043 PROCEDURE	Cancer Institute	

6. * **Usage locations:**

Facility	Building	Usage
Cancer Institute 3010 Lab	Cancer Institute	

7. **Supplier:**
   Human Donor

8. **Quantity:**
   approximately 10 mL from each patient

9. **Personnel that will be handling the material:**
   Donka Milke

10. **Experimental concentration:**
    N/A

11. **Is agent used in animals?**
    ○ Yes ● **No**

12. **Is agent used in humans?**
    ○ Yes ● **No**

13. **Is agent recombinant or synthetic?**
    ○ Yes ● **No**

Example Muse Protocol View: Create/Edit View for Agents

1. **Name:**
   Urine

2. **Agent type:**
   Body Fluid

3. **Classification:**

4. **Is select agent:**
   ○ Yes ● **No**

5. **Risk group:**

6. **Usage Order:**

Viruses or Prions

1. * Identify viruses or prions by strain and source:

	Agent	Biocontainment Level	Strain	Source	Type	Used in Animals	Activities
View	Adenoassociated virus AAV	BSL-2	AAV8	Sponsor	Virus	no	AAV Gene Therapy will be administered intravenously to patients. The gene therapy will be prepared using a BSC per sponsor instructions in the clinical pharmacy.
View	Mysteria Virus	BSL-2	N/A	University of Example Research Lab	Virus	yes	Mice will be inoculated with the Mysteria Virus in a BSC via subcutaneous injection.

2. Describe other viruses or prions:

N/A

Example Muse Protocol View: Create/Edit Viruses or Prions

1. * **Agent:**
   Adenoassociated virus AAV

2. * **Biosafety Containment Assessment:** BSL-2

3. * **Describe the use of the agent:**
   AAV Gene Therapy will be administered intravenously to patients. The gene therapy will be prepared using a BSC per sponsor instructions in the clinical pharmacy.

4. **Strain:**
   AAV8

5. **Where are you obtaining the material from?**
   Sponsor

6. * **Storage locations:**

Facility	Building	Usage
Cancer Institute 4223 PHARMACIST	Cancer Institute	

7. * **Usage locations:**

Facility	Building	Usage
Cancer Institute 11149	Cancer Institute	

8. **Supplier:**
   Sponsor

9. **Quantity:**
   100 mL vial

10. **Personnel that will be handling the material:**
    Katherine Loyd

11. **Experimental concentration:**
    10^7 particles/mL

12. **Is agent used in animals?**
    ○ Yes ● **No**

13. **Is agent used in humans?**
    ● **Yes** ○ No

14. **Is agent recombinant or synthetic?**
    ● **Yes** ○ No

Example Muse Protocol View: Create/Edit Viruses or Prions

1. * **Agent:**
   Mysteria Virus

2. * **Biosafety Containment Assessment:** BSL-2

3. * **Describe the use of the agent:**
   Mice will be inoculated with the Mysteria Virus in a BSC via subcutaneous injection.

4. **Strain:**
   N/A

5. **Where are you obtaining the material from?**
   University of Example Research Lab

6. * **Storage locations:**

Facility	Building	Usage
Cancer Institute 4043 PROCEDURE	Cancer Institute	

7. * **Usage locations:**

Facility	Building	Usage
Cancer Institute 3010 Lab	Cancer Institute	

8. **Supplier:**
   University of Example Research Lab

9. **Quantity:**
   Five 10 mL vials

10. **Personnel that will be handling the material:**
    Katherine Loyd
    Donka Milke

11. **Experimental concentration:**
    N/A

12. **Is agent used in animals?**
    ● **Yes** ○ No

13. **Is agent used in humans?**
    ○ Yes ● **No**

14. **Is agent recombinant or synthetic?**
    ○ Yes ● **No**

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	Supplier	Qty.	Handlers	ECX	Recombinant	Used Anim
Urine	BSL-2	Body Fluid	no	Cancer Institute 4043 PROCEDURE	Cancer Institute 3010 Lab	Human Donor	approximately 10 mL from each patient	Donka Milke	N/A	no	no
Human Blood	BSL-2	Blood	no	Cancer Institute 4043 PROCEDURE	Cancer Institute 3010 Lab	Human Donor	approximately 1-3 mL from each patient	Donka Milke	N/A	no	no
Mysteria Virus	BSL-2	Virus	no	Cancer Institute 4043 PROCEDURE	Cancer Institute 3010 Lab	University of Example Research Lab	Five 10 mL vials	Donka Milke Katherine Loyd	N/A	no	yes
Adenoassociated virus AAV	BSL-2	Virus	no	Cancer Institute 4223 PHARMACIST	Cancer Institute 11149	Sponsor	100 mL vial	Katherine Loyd	10^7 particles/mL	yes	no

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

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).

See Summary of Research and Investigator's Brochure for more information.

Note: This is a great section to describe how the different biohazards will be used together and if any will be used in animals if not already clearly described or if you have a complicated/multi-part experiment.

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).

All human samples and hazards will be transported in a primary and secondary container. The secondary container will have a biohazard label, the PI's name, and the PI emergency contact phone number. A spill kit will be transported with the chemical agent.

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

Sealed rotors will be used and a BSC will be used to mitigate all aerosol risk. All PPE will also be used, such as N-95 respirators when handling human samples.

4. Hazard Containment & Precautions: when will a BSC/CFH be used, PPE required for work, & splash precautions.

A BSC and full PPE will be used for all work performed. Splash precautions and aerosol precautions will be taken to ensure laboratory safety. No biohazards or chemical hazards will be handled outside of containment. A chemical fume hood and full PPE will be used to prepare any chemicals.

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).

Yes, all team members have DOT/IATA Shipping.

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.

The door to all laboratory areas is labelled with a Biohazard sign that describes the agents in use, biohazard level (BSL-2), PI name, PI emergency contact number, and the required PPE. All laboratory equipment that is used to manipulate or store hazards have been labelled with a biohazard sign.

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.

AUP # 1IPROTO202000000123

The animals will be inoculated with the Mysteria virus and receive chemotherapy treatments in various doses as outlined in the AUP. All animal inoculations and dosing will be performed in a BSC using full PPE.

8. Animal Facilities: Cage Cards, Door Signs, & PPE Use for DLAM.

The Door Signs and Cage Cards for DLAM will be labelled for all mice that have received the Mysteria Virus and chemotherapy to communicate the hazard to all staff. This will include the agent name, PPE required, PI name, and emergency contact number on the door sign, and the agent name on the cage card for animals with the hazard. All animal handling should be performed using a lab coat or gown, gloves, goggles or eye shield, and within a BSC.

The animal bedding, urine, and feces are considered hazardous due to the Mysteria virus being present. Thus animal bedding must be dumped in a dump station, handled in a BSC, and put in red biohazard waste per the DLAM SOP 'Handling Cages and Animal Waste Exposed to Hazardous Biologics and Chemicals'.

Cage Cards:
-Mysteria Virus
-Chemical Z

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.

CI.3010 BSC certification date: 8/1/2022
CI.3010 CFH certification date: 8/1/2022

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.

The PI will perform all laboratory specific training and keep documentation for annual laboratory training in the lab binder. Laboratory specific training must be completed by all laboratory members before beginning work, and it is the responsibility of the PI to ensure all staff are properly trained on safe and effective techniques.

Example Muse Protocol

View: SF: Recombinant or Synthetic Nucleic Acids Usage

Recombinant or Synthetic Nucleic Acids Usage

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

yes Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation
no Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic

2. If none of these apply, describe:

Example Muse Protocol

View: SF: Recombinant or Synthetic Nucleic Acid Work Description

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:**
   Clinical trial for Morbus Mysterium using an AAV8 encoding for example gene:

   Drug X is an investigational gene therapy utilizing a novel example construct for the treatment of the disease, Morbus Mysterium.

2. * **For each experiment, list genes, inserts, gene products, and key regulatory elements to be cloned:**
   No cloning will be performed.

3. **Provide a brief description of gene activity and indicate the species of origin for each:**
   Drug X is a synthetic human DNA sequence that mimics healthy function of example gene in the central nervous system that is affected by the Mysteria Virus.

4. **Describe all vectors (plasmids, viruses, RNA/DNA constructs) to be used:** (provide written description and include a map if available)
   AAV8

5. **Upload vector map:**

6. For each experiment identify all applicable host systems to be used:

   Packaging systems: (identify systems)
   N/A

   Microbes: (if E. coli, please indicate if K-12)(identify genus and species)
   N/A

   Tissue/cell culture: (list source and cell type (human, mouse, plant, insect, etc.))
   N/A

   Plant/animal: (identify genus and species)
   N/A

7. * **Describe any attempts to express foreign genes from living organisms:**
   Drug X expresses a synthetic DNA sequence encoding for Example protein.

8. * **List any proteins produced:**
   Example protein.

Example Muse Protocol

View: SF: Human Gene Transfer/Human Clinical Trial(New)

Human Gene Transfer/Human Clinical Trial

1. * **Provide a brief description of the overall goals and research activities:**

The goal of this human clinical trial is to treat Morbius Mysterium caused by the Mysteria virus that is a severe neurodegenerative disease that affects the Example protein.

Drug X is designed to be a safe gene therapy to deliver a targeted expression of genes through the use of an AAV8 vector through a one-time administration.

2. * **Provide a summary of biosafety-relevant preclinical and clinical studies associated with this protocol:**

See the Investigator's Brochure for previous research information and associated clinical studies.

Attach summary documents:

Document	Date Modified
Example Investigator's Brochure.pdf(0.01)	8/10/2022 3:33 PM

3. * **Provide a description of the materials:**

See recombinant section for more information about gene therapy Drug X.

Samples will also be collected from human participants, see Tissues, Blood, or Body Fluids section for more details.

Identify the categories of materials:

Name
There are no items to display

If other, describe:

N/A

4. * **Describe specific procedures for clinical monitoring of the biohazard used in the protocol (e.g. potential for shedding):**

Regular fever watch and laboratory screenings will be performed to check for disease caused by shedding. Clinical monitoring will also be performed for standard bloodborne pathogens.

5. * **Attach all relevant standard operating procedures (SOPs):**

Document	Date Modified
Example Investigator's Brochure.pdf(0.01)	8/10/2022 3:37 PM
Example Laboratory Standard Operating Procedures.pdf(0.01)	8/10/2022 3:38 PM

6. * **Attach clinical protocols:**

Example Clinical Procedure(0.01)

7. Additional Documents:

8. Has IRB review been initiated in CLARA?

● **Yes** ○ No

9. CLARA Number:

123456789

Animals

1. If no related IACUC protocols:

a. Identify the species to be used:

Common Name	Scientific Name	USDA Species
Mouse	Mus	no

b. Identify the locations where animals are being housed or used:

Name	Facility Type	Date of last inspection	Next inspection deadline	Date of scheduled inspection
Sturgis S2406 Lab	Room			

2. Are the animals used in the experiment immunocompromised?

○ Yes ● **No**

3. If yes, describe how:

N/A, see AUP for animal handling information.

4. Which of the following present exposure risks to the protocol team members or animal care personnel?

Animal bite/scratch
Bedding
Blood
Feces
Urine

Example Muse Protocol

View: SF: Risk Group and Containment Practices

Risk Group and Containment Practices

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-2

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-2	ABSL-2	

   NIH Guidelines *rDNA* or synthetic nucleic acids:

Physical Containment	Research Involving Animals	Research Involving Plants	Large-scale Uses of Organisms
BL-2			

Example Muse Protocol

View: SF: Exposure Assessment and Protective Equipment (Biosafety)

Exposure Assessment and Protective Equipment

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

Blood and other potentially infectious material (OPIM) and rDNA Drug X exposure: 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).

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.

Chemical Z Exposure: chemical Z is a reproductive toxin that can cause fertility issues in males and females.
-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).

2. * **Indicate the personal protective equipment that will be used:**

Lab Coats
Eye Protection
Gloves
Gowns
Respirators

3. **If other, specify:**

Gown may be worn in the animal care areas in lieu of a lab coat.

N95 respirator should be worn in patient care areas and when handling patient samples.

Dual Use Research of Concern

1. * **Dual use experiment categories used in this research:** (select all that apply)
   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:**
   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:**
   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.

   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 disinfected via chemical inactivation per DLAM policy.

2. **Autoclave location:**
   Cancer Institute 9142A GLASSWASH/ AUTOCLAVE

3. **Describe the plans for decontamination in the event of a biological accident:**
   Spill of Drug X, Human Samples, or Chemical Z:
   Don appropriate PPE. Cover the spill area with absorbent material. Disinfect the covered spill with 10% bleach and allow to sit for a minimum for 30 minutes. Place all used absorbent material and PPE in biohazard waste. Wash hands for a minimum of 20 seconds with soap and water.

   Items used in small quantities so large spills are not possible.

   rDNA spills will be reported to the PI and UAMS Biosafety Officers for follow-up.

Chemical Hygiene

1. * **Provide relevant hygiene information for each chemical used in the protocol:**

Chemical Agent	Physical Properties	Classification	Toxicology	Routes of Exposure	Other Precautions	Exposure Limits	Monitoring Requirements
Chemical Z (example chemical)	Indicate Physical Properties Here	Acute Toxic (chemical)	Place GHS Classification or other hazard information here, such as carcinogen, mutagen, teratogen, etc.	Mucous membrane Percutaneous injuries Inhalation of aerosols Ingestion	Chemical Fume Hood required for all dilutions	PEL if known	Monitoring requirements if applicable

2. **Justify the use of the selected chemicals:**
Chemical Z is the current treatment for Morbius Mysterium disease.

Example Muse Protocol

View: Create/Edit view for Chemical Hygiene Related Info

1. * **Chemical agent:**
   Chemical Z (example chemical)

2. **Physical properties:**
   Indicate Physical Properties Here

3. **Classification:**
   Acute Toxic (chemical)

4. **Toxicology:**
   Place GHS Classification or other hazard information here, such as carcinogen, mutagen, teratogen, etc.

5. **Routes of exposure:**
   Ingestion
   Inhalation of aerosols
   Mucous membrane
   Percutaneous injuries

6. **Other precautions:**
   Chemical Fume Hood required for all dilutions

7. **Exposure limits:**
   PEL if known

8. **Monitoring requirements:**
   Monitoring requirements if applicable

Chemical Safety Summary

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

	Chemical Agent	CASRN	Quantity	Number of Procedures	Storage Location	Quantity in Storage Location	Fume Hood Certification Date	Lab Phone Number	Attachment
View	Chemical Z (example chemical)		5 mL (max amount in experimentation)	1	Cancer Institute	50 mL (max amount in storage location)	1/1/2099	123-456-7890	

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

Chemical Z will per administered to mice per AUP. Chemical Z will be prepared in the chemical fume hood and will be administered in a type II B2 biosafety cabinet.

3. Describe the methods used:

Subcutaneous injection into mice

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

○ Yes ● **No**

Example Muse Protocol View: Create/Edit view for chemical agent info

1. * **Chemical agent:**
   Chemical Z (example chemical)

2. **Quantity:**
   5 mL (max amount in experimentation)

3. **Number of procedures:**
   1

4. * **Storage location:**
   Cancer Institute

5. **Quantity in storage location:**
   50 mL (max amount in storage location)

6. **Chemical fume hood certification date:**
   1/1/2099

7. **Lab phone number:**
   123-456-7890

8. **Attachment:**

Example Muse Protocol View: SF: Supporting Documents

Supporting Documents

Thank you for completing the information required to submit this protocol to the appropriate Safety Committee.

1. **Attach additional supporting documents:**

Document	Date Modified
There are no items to display	

Take this opportunity to review the information you have provided. It is very important that the responses in this protocol be thorough and specific. Failure to respond to all requested items, to submit all required documents, or complete all personnel requirements will result in a delay in the review of this protocol and may result in the protocol being returned to the protocol team for correction or completion.

Note that this protocol has not yet been submitted for review. Upon completing the information in this protocol and clicking the "Finish" button below, the principal investigator must also click the “Submit” activity from the protocol workspace in order to forward this submission for review.

Example Muse Protocol View: SF: Basic Information

Basic Information

1. * **Select admin office:** Safety

2. * **Title of protocol:**
   Example Muse Protocol

3. * **Short title:**
   Example Muse Protocol

4. * **Summary of research:**
   Example Muse Protocol

   In our research, we will examine the emerging disease, Morbus Mysterium, that affects the immune system and is caused by the Mysteria Virus.

   The protocol will encompass a human gene therapy drug trial and an animal model to examine the mechanism of disease, examine a new gene therapy, and identify best practice dosage for the traditional antiviral treatment.

   1) Gene Therapy: Drug X, is an AAV vector gene therapy that will be administered intravenously to patients enrolled in the clinical trial in the Mystery Disease Clinic located in the UAMS Cancer Institute. This drug will be prepared by clinical pharmacy staff and administered by clinical staff that have all undergone NIH Recombinant DNA training. Patient samples of blood and urine will be collected at 72 hours, 1 week, and 1 month post drug administration. These human samples will be taken to the laboratory located at Cancer Institute for biochemical analysis and quantitative assays for viral shedding.

   2) Animal model: Example mice strain will be used for their overexpression of the Example protein, which is found to play a role in the Mysteria Virus propagation. The mice will be inoculated with the Mysteria Virus in a BSC via subcutaneous injection. The mice will undergo traditional treatment with antiviral agent Chemical Z, however, high doses cause cardiac toxicity. This will be administered in varying dosages to see if an improved dosing model can be found. See the IACUC animal use protocol for the dosage schedule (IPROTO202000000123).

   All sample manipulation and drug manipulation will be performed in full PPE within a Biosafety Cabinet (BSC). All drug administration will be performed in full PPE. Animal handing will be performed in full PPE and a BSC in accordance with DLAM guidance.

Note: Please ensure that the appropriate sections are included for your experiments and the hazards handled. In the example above, the following 'Biosafety Summary' sections should be selected and completed:
-Tissues, Blood, or Body Fluids
-Viruses or Prions
-Recombinant or Synthetic Nucleic Acids
-Human Research Participants
-Animals
-Other (#2 Chemicals)

Example Muse Protocol

5. * **Select appropriate safety review:** Biosafety

6. * **Principal investigator:**
Katherine Loyd

7. **Research Locations:**
UAMS

Protocol Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

Name	Roles	Additional Roles	Involved With Procedures	E-Mail	Phone
Donka Milke	Co-Investigator		yes	DMILKE@UAMS.EDU	5016865299

2. Team member training:

3. External team member information:

Document	Date Modified
There are no items to display	

Example Muse Protocol

View: SF: Funding Sources (not integrated with Grants)

Funding Sources

1. Identify each organization supplying funding for the protocol:

Funding Source	Sponsor's Funding ID	Grants Office ID	Documents
University of Arkansas for Medical Sciences	Occupational Health & Safety	Biosafety Office	

Example Muse Protocol View: SF: Biosafety Summary

Biosafety Summary

1. * Select any items involved in the protocol:

Tissues, Blood, or Body Fluids
Viruses or Prions
Recombinant or Synthetic Nucleic Acids
Human Research Participants
Animals
Other

2. If other, describe items:

Chemicals

Tissues, Blood, or Body Fluids

1. * List Agent, type, and source of all tissues, blood, and body fluids:

	Agent	Biocontainment Level	Source	Type	Used in Animals
View	Human Blood	BSL-2	Human Donor	Blood	no
View	Urine	BSL-2	Human Donor	Body Fluid	no

2. Describe any tissues transplanted between species:

N/A

3. Describe the quantity of tissues and volumes of fluids to be used:

1-3 mL of blood and 10 mL of urine per patient from approximately 20 patients.

Viruses or Prions

1. * Identify viruses or prions by strain and source:

	Agent	Biocontainment Level	Strain	Source	Type	Used in Animals	Activities
View	Adenoassociated virus AAV	BSL-2	AAV8	Sponsor	Virus	no	AAV Gene Therapy will be administered intravenously to patients. The gene therapy will be prepared using a BSC per sponsor instructions in the clinical pharmacy.
View	Mysteria Virus	BSL-2	N/A	University of Example Research Lab	Virus	yes	Mice will be inoculated with the Mysteria Virus in a BSC via subcutaneous injection.

2. Describe other viruses or prions:

N/A

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	Supplier	Qty.	Handlers	ECX	Recombinant	Used Anim
Urine	BSL-2	Body Fluid	no	Cancer Institute 4043 PROCEDURE	Cancer Institute 3010 Lab	Human Donor	approximately 10 mL from each patient	Donka Milke	N/A	no	no
Human Blood	BSL-2	Blood	no	Cancer Institute 4043 PROCEDURE	Cancer Institute 3010 Lab	Human Donor	approximately 1-3 mL from each patient	Donka Milke	N/A	no	no
Mysteria Virus	BSL-2	Virus	no	Cancer Institute 4043 PROCEDURE	Cancer Institute 3010 Lab	University of Example Research Lab	Five 10 mL vials	Donka Milke Katherine Loyd	N/A	no	yes
Adenoassociated virus AAV	BSL-2	Virus	no	Cancer Institute 4223 PHARMACIST	Cancer Institute 11149	Sponsor	100 mL vial	Katherine Loyd	10^7 particles/mL	yes	no

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

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).

See Summary of Research and Investigator's Brochure for more information.

Note: This is a great section to describe how the different biohazards will be used together and if any will be used in animals if not already clearly described or if you have a complicated/multi-part experiment.

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).

All human samples and hazards will be transported in a primary and secondary container. The secondary container will have a biohazard label, the PI's name, and the PI emergency contact phone number. A spill kit will be transported with the chemical agent.

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

Sealed rotors will be used and a BSC will be used to mitigate all aerosol risk. All PPE will also be used, such as N-95 respirators when handling human samples.

4. Hazard Containment & Precautions: when will a BSC/CFH be used, PPE required for work, & splash precautions.

A BSC and full PPE will be used for all work performed. Splash precautions and aerosol precautions will be taken to ensure laboratory safety. No biohazards or chemical hazards will be handled outside of containment. A chemical fume hood and full PPE will be used to prepare any chemicals.

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).

Yes, all team members have DOT/IATA Shipping.

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.

The door to all laboratory areas is labelled with a Biohazard sign that describes the agents in use, biohazard level (BSL-2), PI name, PI emergency contact number, and the required PPE. All laboratory equipment that is used to manipulate or store hazards have been labelled with a biohazard sign.

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.

AUP # 1IPROTO202000000123

The animals will be inoculated with the Mysteria virus and receive chemotherapy treatments in various doses as outlined in the AUP. All animal inoculations and dosing will be performed in a BSC using full PPE.

8. Animal Facilities: Cage Cards, Door Signs, & PPE Use for DLAM.

The Door Signs and Cage Cards for DLAM will be labelled for all mice that have received the Mysteria Virus and chemotherapy to communicate the hazard to all staff. This will include the agent name, PPE required, PI name, and emergency contact number on the door sign, and the agent name on the cage card for animals with the hazard. All animal handling should be performed using a lab coat or gown, gloves, goggles or eye shield, and within a BSC.

The animal bedding, urine, and feces are considered hazardous due to the Mysteria virus being present. Thus animal bedding must be dumped in a dump station, handled in a BSC, and put in red biohazard waste per the DLAM SOP 'Handling Cages and Animal Waste Exposed to Hazardous Biologics and Chemicals'.

Cage Cards:
-Mysteria Virus
-Chemical Z

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.

CI.3010 BSC certification date: 8/1/2022
CI.3010 CFH certification date: 8/1/2022

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.

The PI will perform all laboratory specific training and keep documentation for annual laboratory training in the lab binder. Laboratory specific training must be completed by all laboratory members before beginning work, and it is the responsibility of the PI to ensure all staff are properly trained on safe and effective techniques.

Example Muse Protocol

View: SF: Recombinant or Synthetic Nucleic Acids Usage

Recombinant or Synthetic Nucleic Acids Usage

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

yes	Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation
no	Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic

2. If none of these apply, describe:

Example Muse Protocol

View: SF: Recombinant or Synthetic Nucleic Acid Work Description

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:**
   Clinical trial for Morbus Mysterium using an AAV8 encoding for example gene:

   Drug X is an investigational gene therapy utilizing a novel example construct for the treatment of the disease, Morbus Mysterium.

2. * **For each experiment, list genes, inserts, gene products, and key regulatory elements to be cloned:**
   No cloning will be performed.

3. **Provide a brief description of gene activity and indicate the species of origin for each:**
   Drug X is a synthetic human DNA sequence that mimics healthy function of example gene in the central nervous system that is affected by the Mysteria Virus.

4. **Describe all vectors (plasmids, viruses, RNA/DNA constructs) to be used:** (provide written description and include a map if available)
   AAV8

5. **Upload vector map:**

6. For each experiment identify all applicable host systems to be used:

   Packaging systems: (identify systems)
   N/A

   Microbes: (if E. coli, please indicate if K-12)(identify genus and species)
   N/A

   Tissue/cell culture: (list source and cell type (human, mouse, plant, insect, etc.))
   N/A

   Plant/animal: (identify genus and species)
   N/A

7. * **Describe any attempts to express foreign genes from living organisms:**
   Drug X expresses a synthetic DNA sequence encoding for Example protein.

8. * **List any proteins produced:**
   Example protein.

Example Muse Protocol

View: SF: Human Gene Transfer/Human Clinical Trial(New)

Human Gene Transfer/Human Clinical Trial

1. * Provide a brief description of the overall goals and research activities:

The goal of this human clinical trial is to treat Morbius Mysterium caused by the Mysteria virus that is a severe neurodegenerative disease that affects the Example protein.

Drug X is designed to be a safe gene therapy to deliver a targeted expression of genes through the use of an AAV8 vector through a one-time administration.

2. * Provide a summary of biosafety-relevant preclinical and clinical studies associated with this protocol:

See the Investigator's Brochure for previous research information and associated clinical studies.

Attach summary documents:

Document	Date Modified
Example Investigator's Brochure.pdf(0.01)	8/10/2022 3:33 PM

3. * Provide a description of the materials:

See recombinant section for more information about gene therapy Drug X.

Samples will also be collected from human participants, see Tissues, Blood, or Body Fluids section for more details.

Identify the categories of materials:

Name
There are no items to display

If other, describe:

N/A

4. * Describe specific procedures for clinical monitoring of the biohazard used in the protocol (e.g. potential for shedding):

Regular fever watch and laboratory screenings will be performed to check for disease caused by shedding. Clinical monitoring will also be performed for standard bloodborne pathogens.

5. * Attach all relevant standard operating procedures (SOPs):

Document	Date Modified
Example Investigator's Brochure.pdf(0.01)	8/10/2022 3:37 PM
Example Laboratory Standard Operating Procedures.pdf(0.01)	8/10/2022 3:38 PM

6. * Attach clinical protocols:

Example Clinical Procedure(0.01)

7. Additional Documents:

8. Has IRB review been initiated in CLARA?

● **Yes** ○ No

9. CLARA Number:

123456789

Animals

1. If no related IACUC protocols:

a. Identify the species to be used:

Common Name	Scientific Name	USDA Species
Mouse	Mus	no

b. Identify the locations where animals are being housed or used:

Name	Facility Type	Date of last inspection	Next inspection deadline	Date of scheduled inspection
Sturgis S2406 Lab	Room			

2. Are the animals used in the experiment immunocompromised?

○ Yes ● **No**

3. If yes, describe how:

N/A, see AUP for animal handling information.

4. Which of the following present exposure risks to the protocol team members or animal care personnel?

Animal bite/scratch
Bedding
Blood
Feces
Urine

Example Muse Protocol

View: SF: Risk Group and Containment Practices

Risk Group and Containment Practices

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-2

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-2	ABSL-2	

   NIH Guidelines *rDNA* or synthetic nucleic acids:

Physical Containment	Research Involving Animals	Research Involving Plants	Large-scale Uses of Organisms
BL-2			

Example Muse Protocol

View: SF: Exposure Assessment and Protective Equipment (Biosafety)

Exposure Assessment and Protective Equipment

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

Blood and other potentially infectious material (OPIM) and rDNA Drug X exposure: 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).

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.

Chemical Z Exposure: chemical Z is a reproductive toxin that can cause fertility issues in males and females.
-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).

2. * **Indicate the personal protective equipment that will be used:**

Lab Coats
Eye Protection
Gloves
Gowns
Respirators

3. **If other, specify:**

Gown may be worn in the animal care areas in lieu of a lab coat.

N95 respirator should be worn in patient care areas and when handling patient samples.

Dual Use Research of Concern

1. * **Dual use experiment categories used in this research:** (select all that apply)
   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:**
   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:**
   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.

   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 disinfected via chemical inactivation per DLAM policy.

2. **Autoclave location:**
   Cancer Institute 9142A GLASSWASH/ AUTOCLAVE

3. **Describe the plans for decontamination in the event of a biological accident:**
   Spill of Drug X, Human Samples, or Chemical Z:
   Don appropriate PPE. Cover the spill area with absorbent material. Disinfect the covered spill with 10% bleach and allow to sit for a minimum for 30 minutes. Place all used absorbent material and PPE in biohazard waste. Wash hands for a minimum of 20 seconds with soap and water.

   Items used in small quantities so large spills are not possible.

   rDNA spills will be reported to the PI and UAMS Biosafety Officers for follow-up.

Chemical Hygiene

1. * **Provide relevant hygiene information for each chemical used in the protocol:**

Chemical Agent	Physical Properties	Classification	Toxicology	Routes of Exposure	Other Precautions	Exposure Limits	Monitoring Requirements
Chemical Z (example chemical)	Indicate Physical Properties Here	Acute Toxic (chemical)	Place GHS Classification or other hazard information here, such as carcinogen, mutagen, teratogen, etc.	Mucous membrane Percutaneous injuries Inhalation of aerosols Ingestion	Chemical Fume Hood required for all dilutions	PEL if known	Monitoring requirements if applicable

2. **Justify the use of the selected chemicals:**
Chemical Z is the current treatment for Morbius Mysterium disease.

Chemical Safety Summary

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

	Chemical Agent	CASRN	Quantity	Number of Procedures	Storage Location	Quantity in Storage Location	Fume Hood Certification Date	Lab Phone Number	Attachment
View	Chemical Z (example chemical)		5 mL (max amount in experimentation)	1	Cancer Institute	50 mL (max amount in storage location)	1/1/2099	123-456-7890	

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

Chemical Z will per administered to mice per AUP. Chemical Z will be prepared in the chemical fume hood and will be administered in a type II B2 biosafety cabinet.

3. Describe the methods used:

Subcutaneous injection into mice

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

○ Yes ● **No**

Example Muse Protocol View: SF: Supporting Documents

Supporting Documents

Thank you for completing the information required to submit this protocol to the appropriate Safety Committee.

1. Attach additional supporting documents:

Document	Date Modified
There are no items to display	

Take this opportunity to review the information you have provided. It is very important that the responses in this protocol be thorough and specific. Failure to respond to all requested items, to submit all required documents, or complete all personnel requirements will result in a delay in the review of this protocol and may result in the protocol being returned to the protocol team for correction or completion.

Note that this protocol has not yet been submitted for review. Upon completing the information in this protocol and clicking the "Finish" button below, the principal investigator must also click the “Submit” activity from the protocol workspace in order to forward this submission for review.

Example Muse Protocol

View: Create/Edit Tissues, Blood, or Body Fluids View

1. * **Agent:**
   Human Blood

2. * **Biosafety Containment Assessment:** BSL-2

3. * **Describe the use of the agent:**
   Human blood will be collected from patients in the clinical area that have the virus. The blood will be centrifuged, processed using a BSC and PPE, and undergo biochemical analysis.

4. **Where are you obtaining the material from?**
   Human Donor

5. * **Storage locations:**

Facility	Building	Usage
Cancer Institute 4043 PROCEDURE	Cancer Institute	

6. * **Usage locations:**

Facility	Building	Usage
Cancer Institute 3010 Lab	Cancer Institute	

7. **Supplier:**
   Human Donor

8. **Quantity:**
   approximately 1-3 mL from each patient

9. **Personnel that will be handling the material:**
   Donka Milke

10. **Experimental concentration:**
    N/A

11. **Is agent used in animals?**
    ○ Yes ● **No**

12. **Is agent used in humans?**
    ○ Yes ● **No**

13. **Is agent recombinant or synthetic?**
    ○ Yes ● **No**

Example Muse Protocol View: Create/Edit View for Agents

1. **Name:**
   Human Blood

2. **Agent type:**
   Blood

3. **Classification:**
   Human

4. **Is select agent:**
   ○ Yes ● **No**

5. **Risk group:** RG-2

6. **Usage Order:**

Example Muse Protocol

View: Create/Edit Tissues, Blood, or Body Fluids View

1. * **Agent:**
   Urine

2. * **Biosafety Containment Assessment:** BSL-2

3. * **Describe the use of the agent:**
   Human urine will be collected from patients in the clinical setting and undergo urinalysis and urine pregnancy test in the research laboratory.

4. **Where are you obtaining the material from?**
   Human Donor

5. * **Storage locations:**

Facility	Building	Usage
Cancer Institute 4043 PROCEDURE	Cancer Institute	

6. * **Usage locations:**

Facility	Building	Usage
Cancer Institute 3010 Lab	Cancer Institute	

7. **Supplier:**
   Human Donor

8. **Quantity:**
   approximately 10 mL from each patient

9. **Personnel that will be handling the material:**
   Donka Milke

10. **Experimental concentration:**
    N/A

11. **Is agent used in animals?**
    ○ Yes ● **No**

12. **Is agent used in humans?**
    ○ Yes ● **No**

13. **Is agent recombinant or synthetic?**
    ○ Yes ● **No**

Example Muse Protocol View: Create/Edit View for Agents

1. **Name:**
   Urine

2. **Agent type:**
   Body Fluid

3. **Classification:**

4. **Is select agent:**
   ○ Yes ● **No**

5. **Risk group:**

6. **Usage Order:**

Example Muse Protocol View: Create/Edit Viruses or Prions

1. * **Agent:**
   Adenoassociated virus AAV

2. * **Biosafety Containment Assessment:** BSL-2

3. * **Describe the use of the agent:**
   AAV Gene Therapy will be administered intravenously to patients. The gene therapy will be prepared using a BSC per sponsor instructions in the clinical pharmacy.

4. **Strain:**
   AAV8

5. **Where are you obtaining the material from?**
   Sponsor

6. * **Storage locations:**

Facility	Building	Usage
Cancer Institute 4223 PHARMACIST	Cancer Institute	

7. * **Usage locations:**

Facility	Building	Usage
Cancer Institute 11149	Cancer Institute	

8. **Supplier:**
   Sponsor

9. **Quantity:**
   100 mL vial

10. **Personnel that will be handling the material:**
    Katherine Loyd

11. **Experimental concentration:**
    10^7 particles/mL

12. **Is agent used in animals?**
    ○ Yes ● **No**

13. **Is agent used in humans?**
    ● **Yes** ○ No

14. **Is agent recombinant or synthetic?**
    ● **Yes** ○ No

Example Muse Protocol View: Create/Edit Viruses or Prions

1. * **Agent:**
   Mysteria Virus

2. * **Biosafety Containment Assessment:** BSL-2

3. * **Describe the use of the agent:**
   Mice will be inoculated with the Mysteria Virus in a BSC via subcutaneous injection.

4. **Strain:**
   N/A

5. **Where are you obtaining the material from?**
   University of Example Research Lab

6. * **Storage locations:**

Facility	Building	Usage
Cancer Institute 4043 PROCEDURE	Cancer Institute	

7. * **Usage locations:**

Facility	Building	Usage
Cancer Institute 3010 Lab	Cancer Institute	

8. **Supplier:**
   University of Example Research Lab

9. **Quantity:**
   Five 10 mL vials

10. **Personnel that will be handling the material:**
    Katherine Loyd
    Donka Milke

11. **Experimental concentration:**
    N/A

12. **Is agent used in animals?**
    ● **Yes** ○ No

13. **Is agent used in humans?**
    ○ Yes ● **No**

14. **Is agent recombinant or synthetic?**
    ○ Yes ● **No**

Example Muse Protocol

View: Create/Edit view for Chemical Hygiene Related Info

1. * **Chemical agent:**
   Chemical Z (example chemical)

2. **Physical properties:**
   Indicate Physical Properties Here

3. **Classification:**
   Acute Toxic (chemical)

4. **Toxicology:**
   Place GHS Classification or other hazard information here, such as carcinogen, mutagen, teratogen, etc.

5. **Routes of exposure:**
   Ingestion
   Inhalation of aerosols
   Mucous membrane
   Percutaneous injuries

6. **Other precautions:**
   Chemical Fume Hood required for all dilutions

7. **Exposure limits:**
   PEL if known

8. **Monitoring requirements:**
   Monitoring requirements if applicable

Example Muse Protocol View: Create/Edit view for chemical agent info

1. * **Chemical agent:**
   Chemical Z (example chemical)

2. **Quantity:**
   5 mL (max amount in experimentation)

3. **Number of procedures:**
   1

4. * **Storage location:**
   Cancer Institute

5. **Quantity in storage location:**
   50 mL (max amount in storage location)

6. **Chemical fume hood certification date:**
   1/1/2099

7. **Lab phone number:**
   123-456-7890

8. **Attachment:**