

## Protocol Information

Expiration Date: 12/18/2021

18-200825-T-HSC

### Protocol Detail Report Answered Questions Only

### Title

## 2.3

Maximum limit is 255 characters, be concise.

Note: The title should include reference to procedures and the animal species to be used (e.g. "A Rat Model of Ischemic Stroke.").

### Analysis of autophagy and inflammation in HIV-infected rhesus PBMCs

## Principal Investigator

## 2.4

PI - individual solely responsible for the protocol, its assurances, and can order animals.

Click on the silhouette with the green plus icon below to select the PI. You may type the PI name in the search window.

Select the blue information icon to review your contact information. If it needs updating please email

Department

## 2.5

Select the appropriate department from the drop down list by clicking the green plus icon to the right.

Click the "+" or "-" to expand or collapse the entire list of departments or type the department name in the search window then select "OK".

Molecular Genetics and Microbiology

**Author**

## 2.6

Someone who fills out or works on the request, and is authorized to order animals.

Click on the silhouette with the green plus icon below to select the Author. You may type the Author name in the search window.

**Co-Author**

## 2.7

This person should be someone other than the PI who can access and edit the protocol in the PI's absence.

Click on the silhouette with the green plus icon below to select the Co-Author. You may type the Co-Author name in the search window.

**Created By**

## 2.8

Creator - the person who initially creates the protocol ( auto-populated per the login and cannot be changed) and who may populate documents.

### Protocol Detail Report Answered Questions Only

## Protocol Associates

## 2.9

Personnel who will perform animal work or will handle animal blood or tissue.

Select the appropriate department from the drop down list by clicking the green plus icon to the right.

You may type the Protocol Associate name in the search window and/or check the box to choose that associate then select "OK".

\*In the responsibilities field, indicate if one of the protocol associates is also the Project Coordinator.

There are three different types of personnel who may be working with animals:

**Co-Investigator** - someone who is able to alter this protocol on your behalf.

**Key Associate** - someone who will receive email notifications on status of protocol.

**Authorized to Order Animals** - someone who may order animals for this protocol on your behalf.

<b>Responsibilities</b>	Experiments with isolated rhesus primary immune cells measuring autophagy and inflammation.
<b>Comments</b>	
<input type="checkbox"/> Co-Investigator	<input type="checkbox"/> Key Associate
<input type="checkbox"/> Authorized to Order Animals	

## Animal Handling Training

## 2.10

**Attachments: OACC TrainingPage Personnel Qualifications Final 9-21-16.docx**

Attach the Personnel Qualifications Form here for the PI and all protocol associates by clicking on the paperclip icon to the right:

· Personnel Qualifications Form - training for specific hands-on procedures performed on LIVE VERTEBRATE ANIMALS at UNM (this form is NOT needed for collaborative, display, holding, or tissue protocols).

Protocol associates who are not properly trained may not handle animals and may not be listed on approved protocols.

Click on the links below to access either the Personnel Qualifications Form (hands-on training) or the OACC training website and modules (disable popups on your browser to view attachments).

### 3 Year Re-Write

## 2.11

Does this replace an expiring, expired, or a transfer protocol?

☒ Yes

☐ No

### 2.11.1

Yes

## Source Protocol

### 2.11.1.1

Select the UNM protocol this is replacing from the list by clicking the green plus icon to the right.

You may type any part of the protocol information (protocol number, title, PI, etc.) in the search window.

Reference #	Protocol #	Status	Title	Type
200433	16-200433-T-HSC	Approved	Analysis of autophagy and inflammation in HIV-infected rhesus PBMCs	Renewal

### Protocol Detail Report Answered Questions Only

## Progress Report

### 2.11.1.2

Provide a brief progress report relating to research during the previous approval period.  
Identify the studies described in the previously approved protocol that have already been completed  
Indicate the numbers of animals of each breed/strain/genotype that have already been used  
Reference publications generated out of this research  
Describe how the work proposed in this new protocol will extend the previous studies

The purpose of the proposed work with rhesus PBMCs is to try to test in a relevant primary cellular model some of the hypothesis developed from work with human and rhesus cells lines. This foundational work is not yet complete, and so it has been necessary for us to request rhesus blood to this point. As such, the work proposed in this protocol is an extension of the previously approved work since that work has not yet been completed.

## Associated Protocols

2.12

Select all that apply.

- ☐ UNM Protocols  
☐ External Protocols  
☒ None

### 2.12.3

None

**Office Use Only****Medical Clearance to handle animals, their blood, tissues, or cell lines**

### 3.1

Have the PI and/or all protocol associates been medically cleared to handle animals, their blood, tissues, or cell lines?  
All protocol associates must be medically cleared ANNUALLY. Associates who are not medically cleared may not handle animals and may not be listed on approved protocols.

Office Use Only - checked by OACC staff. Cannot be filled out by PI.

- ☒ Yes  
☐ No

### 3.1.1

Yes

## Online Animal Handling Training

### 3.2

Have the PI and/or all protocol associates completed the required online animal handling courses in the AALAS Learning Library (ALL)?

Office Use Only - checked by OACC staff. Cannot be filled out by PI.

- |                                     |     |
|-------------------------------------|-----|
| <input checked="" type="checkbox"/> | Yes |
| <input type="checkbox"/>            | No  |

### 3.2.1

Yes

### Grant Congruency Review

### 3.3

Is the relevant information in this protocol congruent with the attached vertebrate animal section(s) of the PHS funded grant(s)?

Office Use Only - grant congruency review performed by OACC staff. Cannot be filled out by PI.

- ☒ Yes (required for PHS funded)
- ☐ No (not required for non-PHS funded)

### Protocol Detail Report Answered Questions Only

### 3.3.1

Yes (required for PHS funded)

### Scientific Merit

## Funding

## 4.1

Is this project funded?

☒ Yes

☐ No

### 4.1.1

Yes

### Funding Source

#### 4.1.1.1

Select all funding sources by clicking on the green plus icon to the right.

If your funding source is not listed here, please email [REDACTED] and we will add it for you.

You may click the green plus sign to choose that funding source then select "OK".

NIH/NIGMS

#### 4.1.1.1.1

NIH/NIGMS

### Grant Information and FP#

#### 4.1.1.2

Fill in the following.

Click the green plus icon to the right to add rows to the table.

Title of grant if different from protocol	Grant number/identifier	Grant start date	Grant end date	UNM Identifier (ex: Cayuse#/HSC Pre-Award FP#)
[REDACTED]	[REDACTED]	09/01/2017	08/31/2022	

## PHS Funding

## 4.2

Is this project Public Health Service (PHS) funded?

PHS agencies = National Institutes of Health (NIH), National Science Foundation (NSF), plus the following: ACF, AoA, AHRQ, ATSDR, CDC, CMS, FOH, FDA, HRSA, IHS, SAMHSA

☒ Yes  
☐ No

### 4.2.1

Yes

### Protocol Detail Report Answered Questions Only

### Grant Congruency

#### 4.2.1.1

Attachments: Vertebrate\_animals\_Mandell.docx

Congruency review is required for all PHS agencies = NIH plus the following: ACF, AoA, AHRQ, ATSDR, CDC, CMS, FOH, FDA, HRSA, IHS, SAMHSA

\*Attach the relevant vertebrate animal section(s) of the grant(s) to document congruency between the animal protocol and the vertebrate animal section(s) of the grant by clicking the paper clip icon to the right.

## Conflicts of Interest

### 4.3

Has a Conflict of Interest (COI) form been submitted to the Pre-Award Office for grants associated with this protocol?

☒ Yes☐ No

### 4.3.1

Yes

### Scientific Abstract/Project Overview

## 4.4

**Attachments:**

Include aims/hypotheses/objectives.

The PI may choose to add a [link](#) to their NIH Biosketch, Researchgate, research page, or other summary of relevant publications by clicking on the [paperdip icon](#) to the right or embedding a [link](#) in the text below.

See Attached

## Lay Summary

## 4.5

Address species or taxon of animal(s) using common names, goals, a list of animal procedures, and benefits of the study.

Use non-scientific words.

Eliminate or define abbreviations, technical terms, and jargon.

**Limit 500 words.**

Rhesus macaque blood will be obtained from an outside source [REDACTED] and delivered through [REDACTED]. We will pick up the blood and isolate, grow and expand the white blood cells (WBCs) through a process involving Ficoll Hypaque gradient separation. The procedure will be conducted in a closed laboratory utilizing a biosafety cabinet, safety caps on the centrifuge rotor cups, and careful technique due to the hazards inherent in working with macaque blood. The WBC will be analyzed for key proteins that are involved in the autophagy pathway, which is involved in the protection against microorganisms. All further analysis will be conducted in a tissue culture lab setting.

## Scientific Merit Review

## 4.6

Was this project subject to independent peer review?

☒ Yes☐ No

### 4.6.1

Yes

## Scientific Reviewing Entity

#### 4.6.1.1

List the scientific reviewing entity.

NIH/NIAID Pending RO1, see attached Letter for support- No Deptmental Chair Review needed for Tissue Protocols

### Protocol Detail Report Answered Questions Only

### Collaborative or Tissue Information

## Protocol Type

## 5.1

Select all that apply.

- ☒ Animal Tissue
- ☐ Collaborative (place holder for funding - ALL vertebrate research under this UNM funded project conducted at an external institution)

### 5.1.1

## Animal Tissue

## Reason for Tissue Collection

### 5.1.1.1

Will tissue be collected from live vertebrate animals or will animals be euthanized solely for the purpose of this study? If not, then this qualifies as a tissue protocol and you will fill out the details of your study by selecting "No".

### Examples of Tissue Protocols:

Tissues obtained from a retail source

Shared tissues obtained from animals utilized under a separately approved protocol

Bird or Reptile embryos obtained prior to hatching

Embryos (e.g. Zebrafish up 72 hours post fertilization)

- ☐ Yes
- ☒ No

### 5.1.1.1.2

No

## Animal Tissue

#### 5.1.1.1.2.1

Fill in the following.

Click the green plus icon to the right to add rows to the table.

Species of Origin	Tissue Type	Quantity Requested	Source (e.g. research facility or retail)	UNM Protocol # for tissue origin (if applicable)
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Rhesus Macaque	Blood	12, 250mL shipments	
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## Tissue Uses

#### 5.1.1.1.2.2

Select all that apply.

- ☐ Tissues will be used in a wet lab as training specimens
- ☒ Tissues will be used for in vitro assays
- ☐ Tissues will be inoculated into other laboratory animals
- ☐ Other

**5.1.1.1.2.**  
**2.2**

Tissues will be used for in vitro assays

## Agents and Occupational Risks

### Protocol Detail Report Answered Questions Only

### Occupational Risks Associated with Animals or Tissues Prior to Research Manipulation

## 6.1

Some naive animals or animal tissues pose intrinsic occupational risks to personnel since they may harbor naturally endogenous zoonoses or animals may pose threat of physical injury.

If applicable, please indicate any specific occupational risks associated with animals or animal tissues used under this project and indicate methods to be utilized that will minimize such risks.

Rhesus herpesvirus is a risk to those handling this blood. All rhesus blood will be handled according to

The SOP is attached and in a special binder in our lab and any further personnel who will handle this blood will be first sent for training.

### Biological, Chemical or Radiological Agent Use

## 6.2

Will you be using biological, chemical, or radiological agents of any kind (both hazardous and non-hazardous)?

☒ Yes☐ No

### 6.2.1

Yes

### Agent Type

### 6.2.1.1

Select all that apply.

Biological - bacterial, fungal, parasitic, rickettsial, viral, biological toxins, prions, nucleic acid, cell lines, and primary tissue

Chemical - carcinogens, mutagens, nanoparticles

**Radiological** - administration of radioisotopes or exposure to radiation

Click the links for more information:

☒ Biological☒ Chemical

☐ Radiological

#### 6.2.1.1.1

Biological

### Animal Biosafety Level

#### 6.2.1.1.1.1

Select all that apply by clicking the green plus icon to the right.

ABSL-2

6.2.1.1.1.  
1.1

## ABSL-2

### IBC Protocol Approval

#### 6.2.1.1.1.2

List the Institutional Biosafety Committee (IBC) protocol approval number/ID(s), if required.

### 6.2.1.1.2

Chemical



### Protocol Detail Report Answered Questions Only

## Hazardous Agents

### 6.2.1.2

Please select all hazardous agents (biological, chemical, radiological) that you are going to use in animals under this protocol by clicking on the green plus icon on the right and complete the following:

Add methods for use under the "Comment" field.

Update or change predefined data as necessary to specify use and safety procedures.

You may click the green plus sign to choose that agent then select "OK".

If your agent is not listed here, please email [REDACTED] and we will add it for you.

### Human Immunodeficiency Virus

<b>Comments</b>	For our studies with rhesus cells, we will be using VSV-G pseudotyped (replication incompetent) HIV. Infections will be carried out under BSL-2 conditions. All liquids that might contain pseudotyped virus will be bleached for 10 minutes prior to disposal. All plasticware used with pseudotyped virus will be bleached prior to disposal in biohazardous waste bags for incineration off site.
<b>Precautions</b>	Biosafety practices, containment equipment and facilities are determined by the IBC.
<b>Instructions</b>	Human immunodeficiency virus is the virus that can lead to acquired immunodeficiency syndrome, or AIDS.  The use of this agent requires IBC review and approval. All wild type and recombinant strains must be reviewed and approved by the IBC prior to use.  The use of this agent (& all gene inserts) requires IBC review and approval.

**Nucleic Acid (infectious and non-infectious)**

<b>Comments</b>	Rhesus cells will be transfected with synthetic siRNA to knockdown expression of autophagy/inflammation related proteins.
<b>Precautions</b>	Biosafety practices, containment equipment and facilities are determined by the IBC.
<b>Instructions</b>	<p>Synthetic or Recombinant Nucleic Acid Molecules (infectious and non-infections forms)</p> <p>The administration of recombinant nucleic acid molecules to animals requires IBC review and approval.</p> <p>The use of this agent (&amp; all gene inserts) requires IBC review and approval.</p>

## Formaldehyde

Comments	
Precautions	<p>Formaldehyde is a colorless, strong-smelling gas. Laboratories typically use it as formalin, a methanol-stabilized water solution that contains 37%, 44% or 50% formaldehyde. It is also used as a solid polymer (paraformaldehyde). OSHA has identified formaldehyde as a human carcinogen. Written standard operating procedures (SOP) &amp; safety data sheets (SDS) must be readily available in every lab using formaldehyde. All UNM affiliated personnel using formaldehyde must follow these guidelines.</p> <p>How can I protect myself from formaldehyde?</p> <ul style="list-style-type: none"><li>• Review the formaldehyde MSDS and use the exposure controls it references.</li><li>• Use formaldehyde &amp; its solutions in a fume hood.</li><li>• PPE: Always wear splash goggles, laboratory coats, &amp; impermeable gloves to prevent eye &amp; skin contact.</li><li>• Do not store formaldehyde &amp; its solutions near strong oxidizers.</li><li>• Formaldehyde reacts with hypochlorite to form the potent carcinogen, bis-chloromethyl ether.</li></ul>
Instructions	<p><b>DON'T CLEAN A FORMALDEHYDE CONTAMINATED AREA WITH BLEACH!</b></p> <p>How do I dispose of formaldehyde waste?</p> <ul style="list-style-type: none"><li>• Handle &amp; dispose of formaldehyde as an Extremely Hazardous Waste.</li><li>• Dispose of empty formaldehyde containers as hazardous waste.</li><li>• Dispose of all tissues &amp; carcasses that come into contact with formaldehyde as medical waste.</li><li>• Waste container labeling, disposal request, and removal by SRS can be found on the UNM web site at: <a href="https://srs.unm.edu/chemical-safety/hazardous-waste-collection-request.php">https://srs.unm.edu/chemical-safety/hazardous-waste-collection-request.php</a></li></ul> <p>What do I do if there's a spill or emergency?</p> <ul style="list-style-type: none"><li>• Clean up small spills with absorbent material. Neutralize spill with sodium hydroxide, sodium sulfite, or Spill-X-FP.</li><li>• For large spills, evacuate the area &amp; contact 911 or [REDACTED]. Isolate &amp; control access to spill zone.</li><li>• For dermal &amp; eye exposure, wash area immediately in eyewash/shower for at least 15 minutes.</li></ul>

### Protocol Detail Report Answered Questions Only

### NHP Cells, Tissues and Other Infectious Materials

**Comments** We will just be harvesting blood for ex vivo studies. The animals will not be subjected to hazardous agents.

**Precautions** ABSL-2 practices, containment equipment and facilities. In some applications the use of primary containment equipment is not practical and additional PPE is substituted to reduce the risk of exposure.

The CDC BMBL, Section V. documents the requirements for ABSL-2 (Standard Microbiological Practices, Special Practices, Safety Equipment (Primary Barriers and Personal Protective Equipment) and Laboratory Facilities)

In addition to standard ABSL-2 PPE (e.g., lab coat, gloves, eye protection, shoe covers and bouffant cap), face protection must be worn when working outside of a Biological Safety Cabinet. Chin-length face shields or eye protection (e.g., goggles or glasses with solid side shields) and surgical masks should provide adequate mucus membrane protection.

**Instructions** Non-Human Primate (NHP) cells, blood, lymphoid, neural tissues and other potentially infectious materials should always be considered potentially hazardous.

B virus is a member of the alphaherpesvirus genus (simplexvirus) in the family Herpesviridae. It occurs naturally in macaque monkeys, of which there are nine distinct species. Macaques may have primary, recurrent, or latent infections often with no apparent symptoms or lesions. B virus is the only member of the family of simplex herpesviruses that can cause zoonotic infections. Human infections have been identified in at least 50 instances, with approximately 80% mortality when untreated. There remains an approximate 20% mortality in the absence of timely treatment with antiviral agents.

The use of NHP material alone does not require IBC review and approval. The use of this agent (& all gene inserts) requires IBC review and approval.

### Additional Agents Not Listed Above

### 6.2.1.3

**Attachments: FORMALDEHYDE SDS.pdf**

List any and all agents that were not mentioned above (including non-hazardous agents) and include the information below if applicable:

Description of the agent to include agent classification and risk group (e.g. ABSL2; carcinogen; chemical hazard)

## Precautions and special handling

## Containment and decontamination methods

\*Attach MSDS and/or SOP if available by clicking on the paperclip icon to the right.

### Person Responsible for Biological, Chemical, or Radiological Hazards

#### 6.2.1.4

Give the name of the person(s) in the lab who is/are responsible for the safe handling of hazards and what they are responsible for doing (SDS, training, handling, bioinventory, radiological survey, etc.).

Click the green plus icon to the right to add rows to the table.

Name	Email	Phone	Hazard	Responsibilities
			All	All

### Protocol Detail Report Answered Questions Only

## Waste Management

### 6.2.1.5

Describe your waste management practices (for each agent if different) including any special handling or disposal of cages, bedding, carcasses, waste stream, etc.

All potentially biohazardous waste is disposed of in biohazard-labeled "red" bags. Full bags are taped shut and placed in biohazard bins. The bins are regularly emptied and contents are incinerated. For waste that could potentially contain pseudotyped HIV or herpes B virus, we will disinfect with bleach prior to placing in red bags.

## Assurance Statement

## PI Assurances

## 7.1

Read and select all. The PI must agree to all provisions contained herein. Once selected and saved, this program will require an electronic signature by the PI that will signify the Principal Investigator's agreement with the following conditions and assurances.

The PI must be logged in and must save the checkboxes in order to generate the login that creates the e-signature. No one else may sign.

- ☒ Animals are essential for this project and the study does not UNNECESSARILY duplicate previous experiments.
- ☒ The minimum number of animals will be used to support the goals of this study.
- ☒ All procedures are conducted in a manner to minimize discomfort, distress and pain. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and/or the IACUC.
- ☒ All personnel participating in animal activities on this protocol are adequately trained in the procedures in which they are involved.
- ☒ All personnel are aware of ethical responsibilities associated with animal research activities and procedures for reporting animal welfare concerns.
- ☒ The PI and all personnel associated with this study will follow procedures under the approved protocol and comply with all pertinent institutional, state and federal rules regarding the use of animals in research, testing or education.
- ☒ I understand that if this protocol expires, all animal work under the protocol must cease until a replacement protocol is approved and all remaining animals must be transferred to a holding protocol.
- ☒ All individuals associated with this protocol that will have contact with live animals or with animal tissues or body fluids have been informed of the requirement for participation in the Institution's Employee Occupational Health and Safety Program.

### 7.1.1

Animals are essential for this project and the study does not UNNECESSARILY duplicate previous experiments.

### 7.1.2

The minimum number of animals will be used to support the goals of this study.

### 7.1.3

All procedures are conducted in a manner to minimize discomfort, distress and pain. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and/or the IACUC.

### 7.1.4

All personnel participating in animal activities on this protocol are adequately trained in the procedures in which they are involved.

### 7.1.5

All personnel are aware of ethical responsibilities associated with animal research activities and procedures for reporting animal welfare concerns.

### 7.1.6

The PI and all personnel associated with this study will follow procedures under the approved protocol and comply with all pertinent institutional, state and federal rules regarding the use of animals in research, testing or education.

### 7.1.7

I understand that if this protocol expires, all animal work under the protocol must cease until a replacement protocol is approved and all remaining animals must be transferred to a holding protocol.

### 7.1.8

All individuals associated with this protocol that will have contact with live animals or with animal tissues or body fluids have been informed of the requirement for participation in the Institution's Employee Occupational Health and Safety Program.