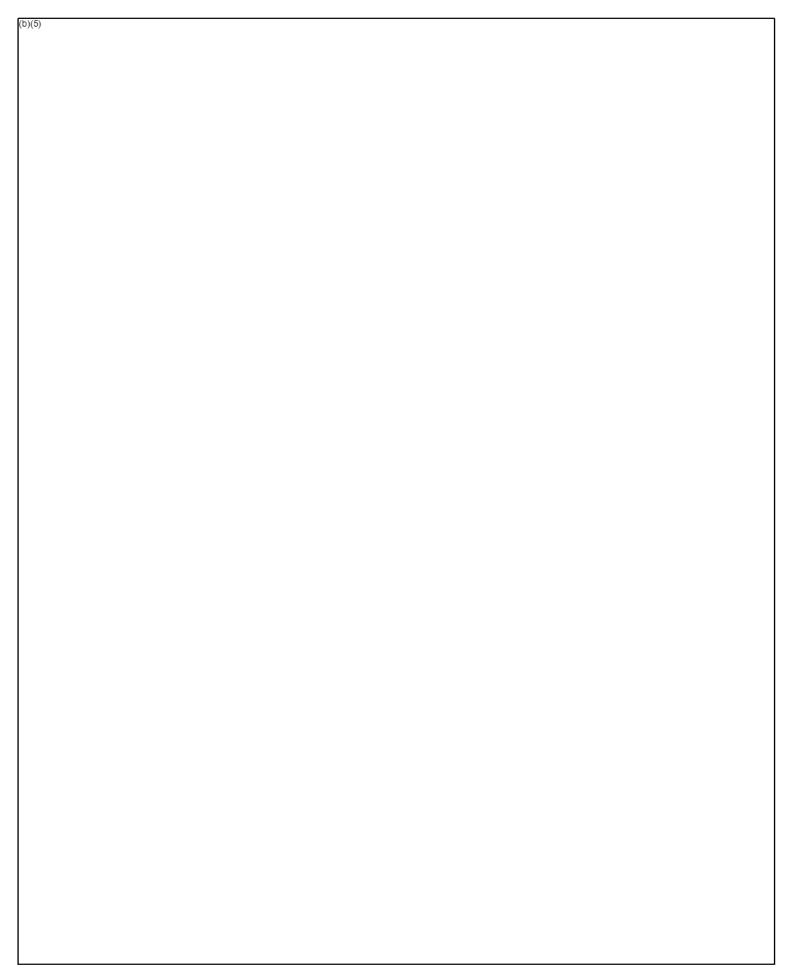
[National Institutes of Health Clinical Center]

Clinical Center (CC) Animal Care and Use Committee

10 CRC 3-2550	
Date: 2/19/20	
Members present:	
Virginia Guptill, PhD, ORSC, Chair Redacted by agreement	Redacted by agreement
Redacted by agreement	1
Lisa Portnoy, DVM, ACP	1
Redacted by agreement	†
Members absent:	
Redacted by agreement	Redacted by agreement
<u> </u>	
5 Members needed for quorum	
Executive Secretary: Redacted by agreement	
Redacted by agreement	
**********	************
Guest Observer:	
Presenters:	
Redacted by agreement	
b)(5)	



(b)(5)
Redacted by agreement
Proposal review Redacted by agreement - Non-Research Maintenance of Experimental Animals.
This proposal was approved with editorial changes.
Vote: Unanimous
Redacted by agreement
Annual review Redacted by General Protocol for Testing Radiopharmaceuticals in Mice and Rats.
The committee agreed to approve this with editorial changes.
 Correct the numbers listed on the top of page 2.

Vote: Unanimous

Approval under Significant Change Policy:	
Veterinary approval:	
Redacted by agreement Procedure addition: Fasting	
Redacted by agreement Procedure addition: Microwave ablation	
Coordinator approval:	
Redacted by Personnel addition: Redacted by	
Redacted by agreement addition: Redacted by agreement	
Procedure space: Redacted by	
Personnel addition Redacted by agreement	
ASPs) Procedure space addition Redacted by ASPs Procedure space addition Redacted by ASPs	
Stipulated Protocol status:	
Redacted by agreement	
Proposal review - Probing Nanomechanics of Inner Ear Tissues. (Breeding protocol)	
Status: Approved	
Redacted by agreement	
Proposal review - Murine Immune Responses to Biomaterials in the Presence and Absence of Trauma.	
Status: Approved	
Redacted by agreement	
Amendment review Redacted by agreement PET and MRI Characterization of Infectious Disease Models.	
Redacted by agreement presented this amendment.	
Status: Approved	
(b)(5)	
Status: Pending	
Redacted by agreement	
<u>Proposal review, Effect of P12K/AKT Inhibition on Pulmonary Vascular Remodeling in the SU-5416/Hypoxia/Normoxia</u>	
Rat Model of Pulmonary Arterial Hypertension.	
Status: Approved	
• •	
(b)(5)	
Status: Pending	
(b)(5)	
Status: Pending	
<u>Designated review status</u> :	
N/A	

Inactivated Protocols:

N/A

Other business:

N/A

Old Business:

N/A

Next meeting: March 18, 2020 9:00am

Virginia Guptill, PhD, ORSC

Webex teleconference due to socia	l distancing.
Date: 3/18/20	
Members present:	
Virginia Guptill, PhD, ORSC, Chair	Redacted by agreement
Redacted by agreement	
Lisa Portnoy, DVM, ACP	
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Redacted by agreement	
- Location by agreement	
Members absent:	
Redacted by agreement	
5 Marsh 2 2 2 1 1 6 2 2 2 2 2 2	
5 Members needed for quorum	
Executive Secretary:	
Redacted by agreement	
*********	*****************
Guest Observer:	
Redacted by agreement	
Drocontors	
Presenters:	
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edacted by agreement	
Amendment review Redacted by agreement	vestigation of the Effects of a programmed death-ligand 1 (PD-L1) Inhibitor and
Semaphorin 5A in a Murine Model	of Pneumonia.

This amendment was approved with editorial changes.

Clinical Center (CC) Animal Care and Use Committee

Minutes of Meeting

The following corrections were sent to the PI:

• Please confirm that no additional animals are being requested.

	Vote: Unanimous
(b)(5)
	Redacted by agreement
	1. Amendment review agreement - Determining the Role of Iron and Nitric Oxide in Cell Free Hemoglobin Induced
	Injury in a Canine Model of S. aureus Pneumonia. Does Haptoglobin Have a Therapeutic Role? The committee agreed to approve this amendment with one clarification to the PI:
	(b)(5)
	Water Harrison and
	Vote: Unanimous 2. Proposal review - Non-Research Holding and Maintenance of Canines.
	The committee agreed to approve with editorial changes.
	The following corrections were sent to the PI: a. Please add page numbers, line numbers and the title in the header.
	b. Please include what circumstances would require contact. If there are none, please put N/A or "none".
	Vote: Unanimous
(b)(5)
- 1	

The committee agreed to approve this amendment with editorial changes.
The following was sent to the PI:
Please define NP
Vote: Unanimous
(b)(5)
Redacted by agreement
Annual review Redacted by Animal Health Surveillance Using Sentinel Animals in the by Shared Animal Facility.
The committee agreed to approve this annual review.
Vote: Unanimous
Redacted by agreement
1. Annual review Redacted by Advanced MRI to Monitor Effects of Neuroprotective Agents for Traumatic Brain
1. Annual review Redacted by Advanced MRI to Monitor Effects of Neuroprotective Agents for Traumatic Brain Injury (TBI) in Rodents.
The committee agreed to approve this annual review.
Vote: Unanimous
2. Annual review agreement Development of Advanced MRI Techniques in Rodents.
The committee agreed to approve this annual review.
Vote: Unanimous
Approval under Significant Change Policy:
Veterinary approval:
N/A
<u>Coordinator approval</u> : N/A
N/A
Stipulated Protocol status:
(b)(5)
Status: Pending
(b)(5)
Status: Pending
Redacted by agreement

Intravital Microscopic Imaging of Nanoformulations.

3. Annual review agreement

Amendment review agreement - Investigation into the Biology, Biochemistry, Immunology, and Therapy of Pneumocystis Infection Status: Approved
Annual review Redacted by agreement
(b)(5)
Status: Pending
DRD DRD Proposal review - Woodchuck Model of Hepatocellular Carcinoma: Development of the Model and Interventional Oncology Applications. Status: Approved
<u>DRD Proposal review</u> - Radiologic Imaging and Interventional Therapies: Development and Assessment of New Technologies and Applications in Swine. Status: Approved
Amendment review agreement Evaluating Immune Response to Minimally Invasive or Non-invasive Ablation in Mice. Redacted by agreement presented this amendment. Status: Approved
Designated review status: N/A
Inactivated Protocols: N/A
Other business: Post Approval Monitoring form was reviewed. There was an adjustment to the monitoring procedure to switch from selecting one protocol per month to meeting with one department per month with a focus on the most complex studies within that department.
Old Rusiness

Old Business:

N/A

Next meeting: April 15, 2020 9:00am Virginia Guptill, PhD, ORSC

Clinical Center (CC) Animal Care and Use Minutes of Meeting Teleconference due to social distancing Date: 4/15/20		
Members present:		
Virginia Guptill, PhD, ORSC, Chair Redacted by agreement	Redacted by agreement	
Lisa Portnoy, DVM, ACP		
Lisa Fortiloy, DVIVI, ACF		
Redacted by agreement		
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Members absent: Redacted by agreement	[Dadastad by agreement	
Reducted by agreement	Redacted by agreement	
5 Members needed for quorum		
Executive Secretary:		
Redacted by agreement		
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Guest Observer:		
Redacted by agreement		
Presenters:		
Redacted by agreement		7
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(b)(5)	

(b)(5)		

(b)(5)
Approval under Significant Change Policy:
Veterinary approval:
N/A
Coordinator approval:
N/A
Stipulated Protocol status:
Redacted by agreement
Proposal review Redacted by agreement - Evaluation of Analgesics, Genes, Neurotransmitters and Diseases in Nociception
and Locomotion.
Status: Approved
Redacted by agreement
- Maintenance of IQGAP1 - Hull Mouse Colony.
Redacted by presented this amendment. Status: Approved
Status. Approved
Redacted by agreement
Amendment review agreement Probing Nanomechanics of Inner Ear Tissues.
Status: Approved
Redacted by agreement
Amendment review Redacted by Investigation of the Effects of a programmed death-ligand 1 (PD-L1) Inhibitor and
Semaphorin 5A in a Murine Model of Pneumonia.
Status: Approved
(b)(5)
Status: Pending
3. Redacted by agreement Amendment review - Intravital Microscopic Imaging of Nanoformulations. (Kupffer cells)
Status: Approved
4. Amendment review agreement - Biomedical Applications of Nanoformulations. (Dox)
Status: Approved
Redacted by agreement
Amendment review Redacted by agreement Status: Approved PET and MRI Characterization of Infectious Disease Models.
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## Designated review status:

The Effects of Prior Checkpoint Inhibitor (CPI) Therapy on Mouse Hepatitis Coronavirus Induced
Pneumonia.

Status: Approved

#### **Inactivated Protocols:**

The Effects of TNF Soluble Receptor, a Selective TNF Inhibitor, on the Inflammatory Effects of *B. anthracis* Cell Wall Peptidogycan in a Rat Model.

#### Other business:

- Semiannual inspection our inspection has been temporarily waived under the OACU campus waiver with OLAW. We will complete this inspection once the social distancing directive has been lifted. The semiannual report was distributed to the committee for review and signature.
- 2. Program review the program description review has been performed by Dr. Portnoy and agreement There were no major changes needed to the program. The description format has been changed according to the format required by AAALAC.
- 3. Scientific Review Policy was reviewed by the committee, no changes were made.
- 4. Chemical Compound form was revised to include a justification section for the principal investigator to complete. If any compounds fall under category 4 as defined by the form (Categories: 1. Compounds are not commercially available as pharmaceutical grade, 2. Compounds are available pharmaceutical grade but not in a formulation suitable for this study(e.g., tablet form when injectable is required), 3. Non------pharmaceutical grade compounds have been used previously and are needed to directly compare new results with the same compounds, 4. Other-provide brief justification below.) The justification section will need to be completed. The form was also amended to include a link to the ARAC guideline for the use of Non-pharmaceutical grade compounds and an excerpt from the Guide was also added.

## Old Business:

N/A

Next meeting: May 20, 2020 9:00am Virginia Guptill, PhD, ORSC

Clinical Center (CC) Animal Care and Use Committee	
Minutes of Meeting	
Teleconference due to social distancing (COVID-19).	
Date: 5/20/20	
Members present:	
Virginia Guptill, PhD, ORSC, Chair Redacted by agreement Redacted by agreement	
Redacted by agreement	
Lisa Portnoy, DVM, ACP	
Redacted by agreement	
Members absent:	
Redacted by agreement	
5 Members needed for quorum	
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Executive Secretary: Redacted by agreement	
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Guest Observer:	
Redacted by agreement	
Presenters:	
Redacted by agreement	
Redacted by agreement	
Amendment review Redacted by agreement PET and MRI characterization of infectious disease models.	
This amendment was approved with the distribution of the revised B3 SOPs.	
Vote: Unanimous	
(b)(5)	

(b)(5)	
Approval under Significant Change Policy: Veterinary approval: N/A	
Coordinator approval: N/A	
Stipulated Protocol status:	
Proposal review Redacted by agreement Preclinical Trials of Novel Therapies for Sickle Cell Disease: Their Effect on Nociception, Disease Progression, Behavior, and Metabolic Markers in Mouse Models of Sickle Cell Disease (SCD). Status: Approved	
p)(5)	
Status: Pending (b)(5)	
Status: Pending	
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Status: Pending	
Designated review status: N/A	
Inactivated Protocols: N/A	
Other Business:  1. OLAW findings report review. Committee discussed responses and agreed upon the proposed response.  Portnoy is to provide a formal response to OACU by June 15 th .  2. Update on other pending COVID projects.	. Dr.
(b)(5)	
<ol> <li>Significant change VVC policy discussed continuation of the policy. The committee agreed we should corwith the policy. Dr. Portnoy to revise document and present at the next meeting.</li> </ol>	ntinue

Old Business:

N/A

Next meeting: June 17, 2020 9:00am

Virginia Guptill, PhD, ORSC

Minutes of Meeting		
Teleconference due to social dista	ncing (COVID-19).	
Date: 6/17/2020		
Members present:	Redacted by agreement	
Virginia Guptill, PhD, ORSC, Chair Redacted by agreement	Treducted by agreement	
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Lisa Portnoy, DVM, ACP		
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Redacted by agreement		
Members absent:	Dedected by agreement	
Redacted by agreement	Redacted by agreement	
5 Members needed for quorum		
Evenueting Connectors		
Executive Secretary: edacted by agreement		
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Guest Observer:		
Redacted by agreement		
Presenters:		
Redacted by agreement		
(b)(5)		
Redacted by agreement		

Clinical Center (CC) Animal Care and Use Committee

Redacted by agreement and Use of an ex-vivo Rat Lung Perfusion N Anthrax Edema and Lethal Toxin on Pulmonary Vascular Endothelial Function.  Dispostion Vote: Approved	Model to Investigate the Effects of
b)(5)	

(b)(5)	
Redacted by agreement	
Redacted by agreement annual review	<u>v</u> – Development of Molecular Therapeutics for Diabetes.
g	modifications to secure approval.
The following modification	
<b>0</b>	
<ul> <li>Emergency form: plea</li> </ul>	se add N/A for answers to questions on lines 33 and 34
Vote: Unanimous	
	ed with the necessary changes and the review was approved through DMR
	su with the necessary changes and the review was approved through Divin
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Approval under Significan	t Change Policy:
Veterinary approval:	
N/A	
<b>Coordinator approval:</b>	
N/A	
Stipulated Protocol status	<u>s:</u>
Redacted by agreement	7
Amendment review	iby Canada Dustana I for Tothing Bedieve and sale in Adia and Sale in Adia
Amenament review	General Protocol for Testing Radiopharmaceuticals in Mice and Rats. (FAP)

Status: Approved

Amendment review agreement Protocol for Molecular Imaging of Cancer Therapy Response. (FAP) Status: Approved
(b)(5)
Status: Pending
(b)(5)
Status: Pending
(b)(5)
Status: pending
Designated review status: N/A
Inactivated Protocols:  Redacted by agreement  Delineating Mechanisms Underlying B. anthracis Edema Toxin's Arterial Relaxant Effects Using the Isolated Aortic Ring Model.
Other Business:  Significant change policy: Dr. Portnoy reviewed the revised policy with the committee. No further changes were needed The policy will be added to our ACUC policies.
Old Business: N/A

Next meeting: July 15, 2020 9:00am

Virginia Guptill, PhD, ORSC

Teleconference due to social	distancing (COVID-19).		
Date: 7/15/2020			
Members present: Redacted by agreement			
	Redacted by agreement		
Lisa Portnoy, DVM, ACP			
Redacted by agreement			
Members absent:			
Redacted by agreement	Redacted by agreement		
Virginia Guptill, PhD, ORSC,	Chair		
Virginia Guptini, i iib, Okse,	Citali		
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5 Members needed for quor	um		
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Executive Secretary: Redacted by agreement	1		
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Guest Observer:			
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Presenters:			
Redacted by agreement			
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Clinical Center (CC) Animal Care and Use Committee

Minutes of Meeting

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Approval under Significant Change Policy: Veterinary approval: N/A
Coordinator approval: N/A
Stipulated Protocol status:
Amendment review Redacted by Radiologic Imaging and Interventional Therapies: Development and Assessment of New Technologies and Applications in Swine.  Status: Approved
Redacted by agreement  Proposal review - Characterizing ACE2 Downregulation Through Binding to SARS-CoV-2 Spike Protein in Mouse Models. Status: Approved
Redacted by agreement  Redacted by agreement  annual review - SU-5416/Hypoxia/Normoxia Rat Model of Pulmonary Arterial Hypertension.  Status: Approved
Amendment review agreement  Status: Approved  Intravital Microscopic Imaging of Nanoformulations. (Liver mets)
Amendment review Redacted by Biomedical Applications of Nanoformulations. (CIA) Status: Approved
annual review w/ amendment - Protocol for Development of Therapeutic Radiopharmaceuticals.  Status: Approved
Designated review status: N/A
Inactivated Protocols: N/A
Other Business: N/A
Old Business:

Next meeting: August 19, 2020 9:00am Virginia Guptill, PhD, ORSC

N/A