

SAFETY Meeting Minutes
UAMS IBC

MEETING TIME RECORDS

Meeting start time: 7/11/2025 12:01 PM

Meeting end time: 7/11/2025 12:47 PM

Meeting type: Virtual

Name of Regular/Alternate Member	Status (Member or Alternate)	Present by Teleconference?
Ha-Neui Kim	Member	Yes
Matthew Jorgenson	Member	No
Robert Hunter	Member	No; vote received via email
Kimberly Murphy	Member	Yes
Lindsey Clark	Member	No
James Douglas	Member	Yes
Amanda Holloway	De Novo	No
James Bishop	Member	Yes; not present for protocol review
Youssef Aachoui	Member	Yes
Jia Liu	Member	Yes
Yuet-Kin Leung	Member	Yes
Melaney Gee	Member	Yes
Mark Manzano	Member	Yes
Christine Simecka Morgan	Member	Yes
Antino Allen	Member	Yes
KyoungHyun Kim	Member	Yes
James Townsend	De Novo	Yes
Shengyu Mu	Member	Yes
Kikumi Ono-Moore	De Novo	Yes
Zhiqiang Qin	Member	Yes

QUORUM INFORMATION

Number of SAFETY members on the roster: 17

Number required for quorum: 9

Quorum: Present

All members present via teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

ATTENDANCE STATUS AND VOTING KEY	
ABSTAIN:	Present for the vote but not voting “For” or “Against.”
ABSENT:	Absent for discussion and voting for reasons other than a conflict of interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflict of interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member serves as a substitute for the regular member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions.

GUEST NAMES
Elisabeth Skaggs, Research Quality CAVHS

Previous Meeting minutes approved: Yes

REVIEW OF SUBMISSIONS

The review and discussion of the protocols listed below included the following elements: the agents involved and their characteristics; types of manipulations planned; the source(s) and nature of the nucleic acid sequences; the host organism(s) and vector(s) to be utilized; whether expression of a foreign gene is intended and, if so, the specific protein(s) to be produced; the containment conditions to be applied, including biosafety level and any special provisions; and the relevant sections of the NIH Guidelines.

All IBC members present were reminded to identify any conflicts of interest as each registration was reviewed.

For each protocol reviewed, it was confirmed that the Principal Investigator (PI) and laboratory personnel have received appropriate training in the safe conduct of research.

Amendment/CR**1. Review of SAMENDCR202500000019**

Title:	Amendment/CR for SPROTO202300000073
Investigator:	Analiz Rodriguez
Submission ID:	SAMENDCR202500000019
Description:	We will use the B16F10OVA-Luc2 cell line, which stably expresses ovalbumin (OVA) and luciferase (Luc2). This cell line was transfected to express OVA, providing a powerful tool to study antigen-specific T cell responses in the context of brain tumors and metastases. The cell line was provided to us by another laboratory (██████████).
Agent Containment:	BSL-2
Applicable NIH Guidelines:	<ul style="list-style-type: none"> • Section III-D • Section III-D-1 • Section III-D-3 • Section III-D-3-a

a. **Determination:** Modifications Required

b. **Required modifications:**

Minor revisions necessary. Please see comments throughout protocol and respond to all queries.

c. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	3
Abstained:	0

De Novo Review**2. Review of SPROTO202500000039**

Title:	SAA as a novel link between inflammation and thrombosis
Investigator:	Andrew Morris
Submission ID:	SPROTO202500000039
Description:	The PI is proposing to use adeno and adeno associated viruses to overexpress the acute phase protein serum amyloid A in mice. The replication defective viruses will be generated by and obtained from the University of Pennsylvania Viral Vector Core Lab. The PI is also proposing to work with mice with homozygous inactivation of the SAA3 gene encoding serum amyloid A. The mice will be used to study the effects of serum amyloid A overexpression and deficiency on platelet

	activation/aggregation and blood clotting.
Agent Containment:	Biological Containment Levels: <ul style="list-style-type: none"> • Human Blood: BSL-2 • Animal Tissue: BSL-2 • Adenovirus: BSL-2 • Adenoassociated virus AAV: BSL-2 • HEK293T Human Cell Line: BSL-2
Applicable NIH Guidelines:	<ul style="list-style-type: none"> • Section III-D-4 • Section III-F • Section III-F-1 • Section III-D

a. **Determination:** Modifications Required

b. **Required modifications:**

Minor revisions necessary. Please see comments throughout protocol and respond to all queries.

c. **Votes:**

For: 14

Against: 0

Recused: 0

Absent: 3

Abstained: 0

De Novo Review

3. Review of SPROTO202500000041

Title:	Role of osteocytes in skeletal and metabolic health
Investigator:	Neha Dole
Submission ID:	SPROTO202500000041
Description:	<p>Metabolic dysfunction in obesity and aging accelerates skeletal deterioration, leading to bone fragility and increasing the risk of osteoarthritis. Osteocytes, as the central regulators of bone remodeling, integrate systemic metabolic cues with local mechanical stress, making them especially vulnerable to dysfunction under these conditions. This project focuses on the molecular signals by which osteocytes contribute to skeletal decline, with particular emphasis on transforming growth factor-β (TGF-β) and Lipocalin 2 (LCN2). By targeting these pathways, the study will test whether restoring osteocyte signaling can improve both bone integrity and metabolic health.</p> <p>Animal studies will include high-fat diet (HFD) feeding to model obesity and destabilization of the medial meniscus</p>

	<p>(DMM) surgery to model post-traumatic osteoarthritis.</p> <p>In vitro studies will use murine osteoblast and osteocyte-like cell lines (OCY454, MLO-Y4, OmGFP66) to define cell-autonomous effects of TGF-β and LCN2. Cells will be transfected with luciferase reporters and shRNAs targeting these signals, using commercially obtained lentiviral vectors. All recombinant materials will be handled under standard BSL-2 containment.</p> <p>Human tissue studies will use de-identified femoral head samples from hip replacement surgeries to assess osteocyte dysfunction in osteoarthritis. Tissues will be processed for RNA, DNA, and protein extraction, as well as histological analyses (IHC and in situ hybridization). All human specimens will be handled in accordance with IRB-approved protocols, with appropriate PPE and waste disposal procedures. No human cells or recombinant materials will be used by [REDACTED].</p> <p>In vivo gene knockdown will be performed using AAV8-shRNA particles targeting TGF-β and LCN2. These vectors have been validated and will be administered by experienced personnel ([REDACTED]). Control and experimental mice will be monitored for changes in body weight, fat mass, circulating biomarkers, and glucose metabolism over time.</p> <p>Regulatory Notes:</p> <p>IRB protocol for human tissue collection is active and approved.</p> <p>All vertebrate animal procedures will be conducted under a valid IACUC protocol.</p> <p>All recombinant DNA, viral vectors, and transfected cells will be used in BSL-2 labs with appropriate containment.</p>
Agent Containment:	<p>Biological Containment Levels:</p> <ul style="list-style-type: none"> • Primary Human Tissue: BSL-2 • Lentivirus: BSL-2 • Adenoassociated virus AAV: BSL-2 • HEK293T Human Cell Line: BSL-2 • MLO-Y4: BSL-2 • MC3T3-E1: BSL-2 • Ocy454: BSL-2 • Mouse Bone Marrow Macrophages: BSL-2

Applicable NIH Guidelines:	<ul style="list-style-type: none"> • Section III-D-1-a • Section III-D-4-b • Section III-D-4 • Section III-F-8-C-VII • Section III-D • Section III-D-3-e • Section III-F-8-C-VIII
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- a. **Determination:** Modifications Required
- b. **Required modifications:**
Minor revisions necessary. Please see comments throughout protocol and respond to all queries.
- c. **Votes:**
- | | |
|-------------------|----|
| For: | 14 |
| Against: | 0 |
| Recused: | 0 |
| Absent: | 3 |
| Abstained: | 0 |

De Novo Review

4. Review of SPROTO202500000044

Title:	Strategies for improving melanoma immunotherapy outcomes (BP269)
Investigator:	Alan Tackett
Submission ID:	SPROTO202500000044
Description:	The protocol involves the modulation of target genes in human (WM-115, WM-266-4, SK-MEL-28) and murine (B16-F1, B16-F10, B16.SIY) melanoma cell lines using a 3rd generation, 4-plasmid, lentivirus system. The PI will use five plasmids: two packaging plasmids (pRSV-Rev, pMDLg/pRRE), one envelope plasmid (pMD2.G), and three transfer plasmids (pLKO.1puro, pLJM1-EGFP, and pLenti-puro). Plasmids will be amplified using one of two E. coli cell lines (NEB stable, TOP10) and Gibson assembly will be performed via PCR on an open bench for cloning the target genes into the transfer plasmid pLJM1-EGFP and for cloning sHRNA into the transfer plasmid pLKO.1puro. Sample to be amplified and ligated will only contain the transfer plasmids which do not contain any lentivirus structural genes, and human transcription factor genes will be prepared in a BSL-2 hood in a 96-well plate with an adhesive cover. The plate will remain sealed and will not be opened outside of the BSL-2 hood. The PI will generate the lentivirus (retrovirus) in

	<p>HEK293T cells. The viruses will then be collected from the medium and applied to the melanoma cell lines in the BSL-2 hood to generate mutant melanoma model cell lines for evaluation in a mouse model of immune checkpoint blockade responsiveness. These studies fall under NIH Guidelines Section III-D and Section III-D-3.</p> <p>This protocol involves the use of murine melanoma YUMM3.3 UVR cells that have been engineered to express the firefly luciferase gene. The YUMM3.3 UVR + Luciferase line was obtained through an inter-site laboratory transfer under an MTA. Cells will be propagated under BSL-2 conditions and subsequently used in tumor implantation studies with C57BL/J6 mice. Following implantation, mice will be treated with a modified low-dose ICI therapy (250 µg anti-PD1 and 100 µg anti-CTLA4 in PBS once weekly, intraperitoneally). This differs from the lab's standard regimen of 250 µg anti-PD1 every three days and 100 µg anti-CTLA4 every two days for two weeks.</p> <p>Tumors will be monitored until they reach a maximum volume of 1000 mm³ or 40 days post-implantation, whichever occurs first. The most aggressive tumors from each group will be processed into single-cell suspensions, purified, and re-implanted into new treatment-naïve recipients (Passage II). This process will be repeated in subsequent passages until tumor growth under low-dose ICI treatment is no longer statistically distinguishable from untreated controls.</p> <p>This study falls under NIH Guidelines Section III-D and Section III-D-3.</p>
Agent Containment:	<p>Biological Containment Levels:</p> <ul style="list-style-type: none"> • Lentivirus: BSL-2 • E. coli: BSL-1 • YUMM3.3 UVR c34 luciferase: BSL-2 • B16.BL6: BSL-1 • B16-F1: BSL-1 • Yumml.7 Murine Melanoma : BSL-1 • B16-F10: BSL-1 • WM-115: BSL-1 • WM-266-4: BSL-1 • Murine T Lymphocytes: BSL-1 • SK-MEL-28: BSL-1 • B16.SIY: BSL-2 • MC38 Murine Colon Carcinoma: BSL-1 • YUMM 2.1: BSL-1 • YUMM3.3: BSL-1 • YUMM3.3.UVR: BSL-1

	<ul style="list-style-type: none"> • Human Embryonic Kidney 293 (HEK293): BSL-1
Applicable NIH Guidelines:	<ul style="list-style-type: none"> • Section III-D-4 • Section III-D • Section III-D-3

a. **Determination:** Modifications Required

b. **Required modifications:**

Minor revisions necessary. Please see comments throughout protocol and respond to all queries.

c. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	3
Abstained:	0

De Novo Review

5. Review of SPROTO202500000030

Title:	Biomarkers in kidney disease (BP175)
Investigator:	John Arthur
Submission ID:	SPROTO202500000030
Description:	<p><u>One of Dr. Arthur's projects focuses on identifying biomarkers for the early detection of Acute Kidney Injury (AKI).</u></p> <p>Candidate biomarkers are evaluated for their use in diagnosis, prediction and progression of kidney disease. The final goal is to develop biomarker-based assay which will guide physicians choosing treatment options for their patients.</p> <p>First, we collect and process a wide variety of biospecimen (blood, urine, tissue, etc.) from patients suffering from various stages of AKI here at UAMS and from collaborating Institutions. Biospecimen are then analyzed and characterized by biochemical methods (ELISA, Western Blot, metabolic and kinetic assays), immunohistochemical methods and proteomic-, metabolomic-, gene expression- analysis to identify candidate biomarkers. Once identified these biomarkers are used to design experiments using rodent kidney injury models and cell-culture to explore physiological processes leading to the disease and its progression. Understanding the underlying processes can help discover points of pharmacological intervention. We will evaluate the use of multiple urinary biomarkers to predict disease progression in severe Acute kidney injury.</p>

	<p><u>A second project of Dr. Arthur will examine ACE 2 Enzyme to predict outcomes in Infection with SARS-CoV-2.</u></p> <p>Covid-19 is a disease caused by SARS-CoV-2, a virus which utilizes the human angiotensin converting enzyme2 (ACE2) to gain entrance into human cells. Between onset of disease and hospitalization is a time delay of 10 days to slow or stop disease progression and we propose to test if ACE2 can be used as biomarker for determining the severity of disease progression. ACE2 levels and activity will be measured as well as various angiotensin fragments produced by it and other proteases.</p> <p>Blood samples will be used to measure enzymatic activity of ACE2 in plasma and the abundance of ACE2 in plasma will be measured by ELISA. A second plasma sample will receive a cocktail of inhibitors of ACE2 and other proteases involved in processing of angiotensinogen or angiotensin. Different angiotensin fragments produced by ACE2 and other proteases will be assessed by proteomic analysis at the UAMS Proteomics Core Facility. A third sample of blood will be collected for analysis of gene polymorphisms of ACE2, TMPRSS2 and CatB/L. Genes will be sequenced in the UAMS Sequencing Core Facility.</p>
Agent Containment:	<p>Biological Containment Levels:</p> <ul style="list-style-type: none"> • Animal Serum: BSL-2 • Animal Tissue: BSL-2 • Human Nasal Swab: BSL-2 • Human Blood: BSL-2 • Urine: BSL-2 • Human Plasma: BSL-2 • Human Serum: BSL-2 • Primary Human Tissue: BSL-2 • Human Saliva: BSL-2 • Human Stool: BSL-2 • HEK293T Human Cell Line: BSL-2 • Animal Cells: BSL-2 • HK-2 (Human Kidney 2): BSL-2 • RPTECs (human primary renal proximal tubule epithelial cells): BSL-2 • AML12 CRL-2254 Murine Cell Line: BSL-2
Applicable NIH Guidelines:	Exempt per Appendix C-VIII

a. **Determination:** Modifications Required

b. **Required modifications:**

Minor revisions necessary. Please see comments throughout protocol and respond to all queries.

c. Votes:

For: 14
Against: 0
Recused: 0
Absent: 3
Abstained: 0

De Novo Review**6. Review of SPROTO202500000043**

Title:	Genetic modifications of cells by retrovirus transduction (BP374)
Investigator:	Yong-Chen Lu
Submission ID:	SPROTO202500000043
Description:	The purpose of this biosafety protocol is to use retrovirus as a research tool for expressing desired genes in cells. Gene sequences obtained from research or public databases will be synthesized and cloned into a retrovirus vector. Retroviruses carrying these genes will be produced by a producing cell line, and these retroviruses will be used to transduce T cells or tumor cell lines. As a result, transduced T cells and tumor cell lines will express the desired genes for the use of experiments. The experiments include testing the functions of these genes in T cells in vitro and testing the survival of tumor cells carrying these genes in vivo. The long-term goal of the research is to develop new T cell-mediated immunotherapy for cancer and to improve the current immunotherapy treatments.
Agent Containment:	Biological Containment Levels: <ul style="list-style-type: none"> • Animal Tissue: BSL-2 • Animal Blood: BSL-2 • Retrovirus: BSL-2 • 293GP Cell Line: BSL-2 • B16F10 Murine Melanoma: BSL-2 • Human T Cells (Lymphocytes): BSL-2 • EBV-transformed B Human Cell Line: BSL-2 • COS-7 (African green monkey kidney fibroblast-like cell line): BSL-2
Applicable NIH Guidelines:	<ul style="list-style-type: none"> • Section III-E-1 • Section III-F-8

a. **Determination:** Modifications Required

b. **Required modifications:**

Minor revisions necessary. Please see comments throughout protocol and respond to all queries.

c. Votes:

For:	14
Against:	0
Recused:	0
Absent:	3
Abstained:	0

REVIEW OF OTHER AGENDA ITEMS

1. Two safety incidents involving injuries were reviewed by the committee. No further requirement to report beyond committee at this time.
2. Dr. Simecka led a discussion regarding revising the approval process for safety protocols involving the use of chemical reagents and drugs in animals. The committee approved the implementation of the new process, which will take effect immediately.