SAFETY Meeting Minutes
UAMS IBC

MEETING TIME RECORDS

Meeting start time: 9/5/2025 12:05 PM
Meeting end time: 9/5/2025 13:04 PM
Meeting type: Virtual

Name of Regular/Alternate Member	Status (Member or Alternate)	Present by Teleconference?
Ha-Neui Kim	Member	No
Matthew Jorgenson	Member	Yes
Robert Hunter	Member	Yes
Kimberly Murphy	Member	No
Lindsey Clark	Member	Yes
James Douglas	Member	No
Amanda Holloway	Ex Officio	No
James Bishop	Member	No
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	No
Antino Allen	Member	Yes
KyoungHyun Kim	Member	Yes
James Townsend	Ex Officio	Yes
Shengyu Mu	Member	No
Kikumi Ono-Moore	Ex Officio	No
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 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.

De Novo Review

1. Review of SPROTO202500000062

Title:	Epigenetic mechanisms associated with the development, maintenance, and resolution of chronic pain (BP253)
Investigator:	Kimberly Stephens
Submission ID:	SPROTO202500000062
Description:	Persistent pain often develops following nerve injury when primary sensory neurons show complex activity-dependent plasticity and ectopic discharges, which may be the result of epigenetic mechanisms. Epigenetic mechanisms help regulate alterations in cellular phenotype that do not involve changes to the DNA sequence, and generally serve as an avenue for environmental factors to influence the behavior of the genome. Accordingly, epigenetic mechanisms are well-established regulators of a wide variety of physiological (e.g., transcriptional control) and pathological processes (e.g., progression of cancer). One major pathway of epigenetic modulation is the targeted addition or removal of small chemical modifications on individual nucleosomes, each comprised of ~150 base pairs of DNA wrapped around histone proteins. Such epigenetic changes can alter positioning of specific nucleosomes, and impact the binding of transcription factors to regulatory elements of specific genes like enhancers and promoters, thus modulating transcription. Epigenetic involvement in persistent pain after peripheral nerve injury remains largely unexplored. Our overall goal is to understand how epigenetic mechanisms in the dorsal root ganglion contribute to the development, maintenance, and resolution of chronic pain. Specifically, we are interested in the identification and functional consequences of changes in chromatin accessibility at cis-regulatory regions promote transcription and cellular response. We use surgical and non-surgical rodent models to study inflammatory and neuropathic pain conditions and assess mechanical and thermal pain behaviors in these models including the evaluation of pharmaceutical and electrophysical treatment to alleviate pain. We use next-generation sequencing based assays and well-established biostatistical methods to preprocess and comprehensively analyze sequencing data. We complement these approaches with a variety of molecular biology approaches using in vitro, ex vivo, and in vivo systems and necessary collaborations to comprehensively evaluate phenotypic changes that alter cellular function.

Agent Containment:	Biological Containment Levels: • Human Blood: BSL-2+ • Animal Tissue: BSL-2 • Lentivirus: BSL-2+ • E. coli: BSL-2 • E. coli: BSL-2 • Human Embryonic Kidney 293 (HEK293): BSL-2 • HEK293T Human Cell Line: BSL-2 • 50B11 Rat Cell Line: BSL-2 • 50B11 Rat Cell Line: BSL-2
Applicable NIH Guidelines:	• Section III-D-4 • Section III-D • Section III-D-3 • Section III-D-3-a

a. **Determination:** Modifications Required

b. **Required modifications:**
Revisions required. Please review and respond to all comments throughout the protocol.

Contact BSOs with any questions. Thank you!

c. **Votes:**

For:	11
Against:	0
Recused:	0
Absent:	6
Abstained:	0

De Novo Review

2. Review of SPROTO202500000065

Title:	Molecular pathogenesis of staphylococci (BP135)
Investigator:	Chia Lee
Submission ID:	SPROTO202500000065
Description:	Staphylococcus aureus is an important human pathogen causing many diseases. The organism produces many virulence factors required for infections, which are regulated by various regulators. How virulence genes are coordinately regulated is not fully understood. In one project, we will study how virulence factors are regulated by various regulators. We use various genetic and molecular methods to perform mutant construction, gene cloning, genetic complementation, and biochemical analyses to understand virulence regulation in

	vitro. We will then study how the regulation of these virulence factors impacts the ability of bacteria to cause diseases using animal models based on our understanding from the in vitro studies. Different animal models, including a mouse skin infection model and a mouse bacteremia model, will be used depending on the phenotypic traits affected by the gene under study. A general approach is to compare the effect of virulence between the wild-type bacterial strain and its isogenic mutant by assessing the bacterial counts, tissue damage, or severity of the disease. In some studies, we will isolate RNAs from bacteria from bacterial cultures and from infected tissues. In another project, we study biofilm formation in staphylococci. Biofilms are bacterial community that forms on solid surfaces encased within a biofilm matrix. We will use the same in vitro methods described above to study how biofilm formation is regulated. We also use a mouse biofilm model to study genes involved in biofilm formation in vivo.
Agent Containment:	Biological Containment Levels: • Staphylococcus aureus: BSL-2 • E. coli: BSL-1 • Animal Tissue: BSL-2
Applicable NIH Guidelines:	• Section III-F-3 • Section III-F • Section III-F-1 • Section III-F-4 • Section III-F-8

a. **Determination:** Modifications Required

b. **Required modifications:**
Minor revisions necessary. Please review and respond to all comments throughout the protocol.

Contact BSOs with any questions. Thank you!

c. **Votes:**

For:	11
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Initial Protocol

3. Review of SPROTO202500000061

Title:	ST-503 gene therapy for refractory pain due to idiopathic small fiber neuropathy (iSFN)
Investigator:	Johnathan Goree
Submission ID:	SPROTO202500000061
Description:	The overall objective is to determine safety and tolerability of a one-time dose of ST-503 administered intrathecally by lumbar puncture (LP) to subjects with refractory pain due to idiopathic small fiber neuropathy (iSFN) without impaired or abnormal glucose metabolism. ST-503 is a recombinant adeno-associated viral serotype 9 (AAV9) Nav1.7 gene therapy for the treatment of subjects with idiopathic small fiber neuropathy (iSFN), a peripheral neuropathy. Modulating Nav1.7 has emerged as a promising candidate for analgesic drug development for people with iSFN. Therefore, lowering Nav1.7 via selective repression of SCN9A using engineered zinc finger repressors (ZF-Rs) would reduce expression of Nav1.7. ST-503 will be a lumbar puncture (LP) injection.
Agent Containment:	Biological Containment Levels: • Human Stool: BSL-2 • Urine: BSL-2 • Human Saliva: BSL-2 • Human Blood: BSL-2 • Adenoassociated virus AAV: BSL-2
Applicable NIH Guidelines:	• Section III-C • Section III-C-1

a. **Determination:** Modifications Required

b. **Required modifications:**
Minor revisions necessary. Please review and respond to all comments throughout the protocol.

Contact BSOs with any questions. Thank you!

c. **Votes:**

For:	11
Against:	0
Recused:	0
Absent:	6
Abstained:	0

REVIEW OF OTHER AGENDA ITEMS

1. An update was provided on the status of changes made in response to the NIH Transparency Guidelines. Changes to the minutes were made to remain in compliance with NIH; changes were approved by the committee.

2. The committee reviewed the proposed IBC Roles & Responsibilities document, which will be added as an attachment to the Biosafety Manual upon approval.

3. Changes to reviewer roles were discussed. Reviewers will begin resolving comments in the protocol upon PI response to requested modifications. The IBC Workflow in Muse document was provided to committee members for review.