



SAFETY Meeting Minutes
 IBC Committee
 Zoom

MEETING TIME RECORDS

Meeting start time: 1/14/2026
 3:00 PM
Meeting end time: 3:28 PM

VOTING MEMBER ATTENDANCE

Name of Regular/Alternate Member	Status (Member or Alternate)	Present by Teleconference?
Karl McKinstry	Member	X
Gregory Danyluk	Member	X
Melina Kinsey	Member	X
Kyle Rohde	Member	X
Stanley Haimes	Member	Absent
Hubert Salvail	Member	X
Judith Hecker	Member	X
Lane Coffee	Member	X
Yulia Gerasimova	Member	X
Teresa Krisch	Member	X

QUORUM INFORMATION

Number of SAFETY members on the roster: 10
Number required for quorum: 5

All members present by 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 conflicting interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflicting interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member substitutes 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.
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GUEST NAMES
Sophia Vermeulen, Biosafety Specialist

Previous Meeting minutes approved: Yes, for November and December 2025.

REVIEW OF SUBMISSIONS

Initial Protocol

1. Review of SPROTO20250000029

Title:	Comparison of DNA methylation patterns in infants with heart disease - Nelson
Investigator:	Jennifer Nelson
Submission ID	SPROTO20250000029
Funding:	• Name: Nemours Children's Hospital, Grant Office ID: , Funding Source ID:
Agents:	• Muscular Tissue • Human Derived Blood and Blood Types
Agent Containment:	Biological Containment Levels: • Human Derived Blood and Blood Types: BSL-2 • Muscular Tissue: BSL-2
Applicable NIH Guidelines:	None

- a. **Description:** Congenital heart defects (CHDs) often arise from unknown origins. While there are certainly underlying genetic mutations in some cases, the vast majority (> 70%) of cases have not been associated with known genetic mutations. Instead, environmental factors such as alcohol, drugs, toxin exposure, and other forms of stress during early pregnancy have been associated with increases in the incidence and severity of various forms of CHDs. It is not clear how these environmentally-induced forms of CHD arise, but recent work has shown that some (e.g., alcohol) cause epigenetic changes such as altering DNA and histone methylation patterns, which can, in turn, lead to altered or abnormal gene expression patterns. Notably, several forms of CHD, including Tetralogy of Fallot, also have altered DNA methylation patterns. These epigenetic changes often persist long after the inducing agent is gone, and thus can serve as potential diagnostic markers (“epigenetic signatures”) that may enable earlier and more specific diagnosis of environmentally-induced forms of CHD that could then be used to guide prevention efforts and provide better treatment options for afflicted patients, leading to improved patient outcomes.
- b. **Determination:** Approved with Modifications Required
Moved: Judy Hecker
Second: Melina Kinsey
- c. **Required modifications:**
1. Tissues, Blood, or Body Fluids

- Add buccal swabs, Use the % sign to search for Buccal in the list of agents (i.e. %Buccal).

d. Votes:

For: 9
Against: 0
Recused: 0
Absent: 1
Abstained: 0

De Novo Review

2. Review of SPROTO202500000031

Title:	MOLECULAR ASPECTS OF UROLOGIC INVESTIGATION - Seth
Investigator:	Abhishek Seth
Submission ID	SPROTO202500000031
Funding:	<ul style="list-style-type: none"> • Name: Nemours Children's Hospital, Grant Office ID: , Funding Source ID: • Name: Nemours Foundation, The, Grant Office ID: , Funding Source ID:
Agents:	<ul style="list-style-type: none"> • Escherichia coli K12 or derivative • Reproductive Tissue • Human Derived Blood and Blood Types • Other Cell Lines • HS68 • Human foreskin fibroblast • Lentivirus • Adenovirus – laboratory
Agent Containment:	<p>Biological Containment Levels:</p> <ul style="list-style-type: none"> • Human foreskin fibroblast: BSL-1 • Other Cell Lines: BSL-1 • Escherichia coli K12 or derivative: BSL-1 • HS68: BSL-1 • Adenovirus – laboratory : BSL-2 • Lentivirus: BSL-2 • Human Derived Blood and Blood Types: BSL-2 • Reproductive Tissue: BSL-2
Applicable NIH Guidelines:	<ul style="list-style-type: none"> • Section III-D-1-a • Section III-F-8-C-I • Section III-F • Section III-F-8-C-II • Section III-F-1

	<ul style="list-style-type: none"> • Section III-F-5 • Section III-D-1 • Section III-F-8-C-VII • Section III-F-8
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a. **Description:** We wish to test the hypothesis that congenital genitourinary defects result from gains or losses of specific development related genes. We will test a variety of growth related, DNA replication/repair and steroid receptor related genes for mutations by PCR amplification of RNA or RTPCR amplification followed by direct sequencing. We will also analyze expression of genes in primary and immortalized cells and male reproductive tissues (both adult and during development: testis, sperm, penis, foreskin, seminal vesicles, white blood cells etc.). We will perform cloning or purchase vector clones for the following genes for these studies. The genes chosen for analysis are the androgen receptors, genes involved in steroid biosynthesis or metabolism (StAR, CYP24), DNA replication/repair or development that might impact steroid receptor action, DNA replication/repair or be involved in carcinogenesis, spermatogenesis or abnormal development itself. These genes include the androgen receptor, HOX genes, KCTD13, CUL3, WNT4, PRSS50, SOX9, RHOA, FOXL2, GAPDH, Y chromosome genes (DAZ, SMCY, SMCX, DAX), DMPK, other genes in the ubiquitination pathway. Genes involved in urologic development and adult function include OTX1, SUCLA2, VAMP7, ACDY19, MAZ, KANK1, CRKL, WT1, CABL, KCDT13, FOXP1, DDR1, E2F1, P53, NELL1, CTDSPL, ghrelin, GHSR, and other candidate genes as identified during the course of gene discovery. We will also use expression vectors in transient and stable transfection assays to examine the effects of the androgen, as well as the ubiquitination pathways to define gene regulation by steroid hormone receptors. The expression vectors to be used include GRELuc, PC3Luc, PBLuc, various androgen receptor mutationLuc all cloned into PBKRSV. We will also use MMRMutL, MMRMutS, AR and CYP24 cloned into bluescript. We use cloning vectors TOPO TA with DH5alpha cells. Viral approach will also be used in these studies to over-express or knockdown the expression of candidate genes. This will be achieved by using ready-to-use lentiviral particles containing shRNA of the genes of interest or replication-deficient adenoviral vectors containing cDNA of interest under the control of CMV promoter. No amplification or titration of the lentiviral or adenoviral vectors will be done in our lab. After infection, expression levels of the candidate genes as well as their known targets will be monitored by RTPCR and western blots.

b. **Determination:** Approved with Modifications Required

Moved: Karl McKinstry

Second: Lane Coffee

c. **Required modifications:**

1. Exposure Assessment and Protective Equipment

- Address BBP possibility from patient samples in risk section

d. **Votes:**

For: 9

Against: 0

Recused: 0
Absent: 1
Abstained: 0

REVIEW OF OTHER AGENDA ITEMS

This meeting is the last meeting for Gregory Danyluk for he retired and resigned from the IBC Committee. The IBC Chair and BSO will conduct a search for a new outside committee member.