THE WISTAR INSTITUTE IBC 3rd Quarterly Meeting Minutes

September 10, 2025
11:00AM – 12PM
Hybrid Meeting

Members' Present: (Quorum = 6 members)
Ami Patel, Chair,
Roma Maraj-Owen, Director of Laboratory Operations and Environmental Health and Safety
Denise DiFrancesco, WI Animal Facilities Director
Lauren Duffy, WI Animal Facilities Associate Managing Director.
Rebecca Spangenberg, Non-Affiliated Assist. Prof.
Erick Gagne, Non-Affiliated Assist. Prof
Michelle Ho, WI Biosafety Officer

Non-Voting Members Present:
Maurice Brandon, WI Science Administration Assistant

Members Absent:
Sonali Majumdar, WI PI
Paul Lieberman, WI PI
Yulia Nefedova, WI PI
Peter Scarpati, WI VP Operations

Guests Present:
.

1.0 Call to Order
- 1.1 The meeting was called to order at 11:04 AM

2.0 Welcome and introductions - Wistar affiliated and non-affiliated members
- 2.1 Dr. Ami Patel recognized each member and thanked them for their participation. The members present constituted a quorum
- 2.1 Dr. Ami Patel introduced Dr. Erick Gagne, reintroduced Ms. Rebecca Spangenberg, as well as the present members.

3.0 Review and Approval of Previous 2nd Quarter 2025 Meeting (June 11, 2025) Minutes.
- 3.1 Motion to approve was made by Roma Maraj-Owen, seconded by Lauren Duffy. Minutes of the Second Quarter meeting (June 11, 2025) were approved by those present at the meeting.

4.0 Discussion of observed Violations / Exposures (Michelle Ho, Biosafety Officer, and Maurice Brandon, Science Administration Asst.)
- 4.1 No observed violations.
- 4.1 Denise DiFrancesco questioned what we consider "violations" in regard to the IBC Committee. Roma Maraj-Owen discussed factors that constitute the necessity of reporting to the IBC committee and how those findings are reported.

5.0 Quarterly Review of Approved IBC Registration during the 3rd Quarter of 2025 (6/11/2025-09/09/2025) Mr. Brandon discussed the 13 IBC Registrations that were approved during the second quarter and their status.

5.1 For the registrations below, the committee discussed , where relevant, the characteristics of the agent, the types of manipulations planned, the source(s) of the nucleic acid sequences, host(s) vector(s) to be used and whether there were attempts planned to obtain expression of a transgene, and if so, the function of the protein that would be produced.

22506651 - Maldini, Colby, ***Developing immunotherapies for HIV cure and cancer***

- The central objective is to develop and assess immunotherapies for HIV cure and cancer. To do so, this work leverages the use of 1) replication competent HIV isolates to infect human T cells both in vitro and in vivo and 2) immortalized cancer lines modified with single-cycle replication incompetent lentiviruses to permit in vivo tracking. Then we will treat HIV-infected T cells or cancer cell lines with chimeric antigen receptor (CAR) modified immune cells and/or depleting monoclonal antibodies, evaluating their ability to eliminate infection and tumor. CAR modified immune cells will be generated through lentiviral transduction and through delivery of mRNA encoding base editor and single-guide RNA(s). In addition, to facilitate in vitro characterization of our cure strategies, we will create target cell lines by modifying immortalized cancer cell lines using lentiviral vectors.
- NIH Guidelines Section III-D, BSL 2
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22506652 - Aird, Katherine, ***Metabolic landscape of cancer***

- This lab aims to overexpress and/or knockdown genes involved in metabolism and cell cycle control to understand how these processes influence each other. We will package 3rd generation lentiviruses using HEK293FTs and 3 packaging plasmids. We will transduce human or mouse established cancer cell lines. These will be used for downstream assays, including injecting cells into mice.
- NIH Guidelines Section III-F, BSL 2
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22507653 - Altieri, Dario, ***Role of Syntaphilin (SNPH) and Parkin in prostate cancer Phase 2***

- This lab is investigating the role of Parkin in tumor progression. Parkin protein is lost in tumors. We need an inducible system so we can restore Parkin expression at a certain time point to study the effect of Parkin during tumor growth. We will transduce mouse mammary tumor and prostate tumor cell lines to express Parkin and observe the effect of the transduced Parkin in mice.
- NIH Guidelines Section III-D, BSL 2
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22507654 - Patel, Ami, ***Evaluation of DNA vaccines against antimicrobial resistant bacteria IBC Registration***

- This lab studying the role of plasmid DNA vaccines against antimicrobial resistant bacteria. WE have selected vaccine immunogens that are potential bacteria virulence factors (their presence can contribute to increased pathogenesis and disease). Our

alpha hemolysin based vaccines have deletions in the catalytic domain so that they are functionally inactive.
- NIH Guidelines Section III-E, BSL 1
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22507655 - Montaner, Luis, ***Gene Vectors for protein expression***
- This lab will use plasmids encoding monoclonal antibodies, e-CD4 Ig, or negative control vectors in experiments targeting HIV-infected cells. These proteins were initially isolated from persons living with HIV and have the capacity to bind envelop and as such neutralize particles and/or bind to infected cells. Proteins to be expressed have different capabilities for HIV neutralization than those normally present in persons living with HIV or elicited by vaccination. Therefore, in order to circumvent natural immune responses that are in general unable to generate these high binding/neutralizing proteins, we can encode them on DNA plasmids by replacing the Fc human constant region (component of antibody that does not bind antigen) to mouse constant region to increase their effector function in mice and deliver the DNA to the mouse muscle which will then produce them.
- NIH Guidelines Section III-E, BSL 1
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22507656 - Li, Qingsheng, ***Preparation and characterization of mRNA-LNP vaccines***
- The mRNA-LNP vaccines have a profile of safe, high adjuvant property, immunogenicity, and potent efficacies against many pathogens in rodents, non-human primates (NHP) and clinical trials. We will use viral Multiple-epitope Proteinase Cleavage Sites (MEPCS) from Simian Immunodeficiency Virus (SIV) or three epitopes from the Lymphocytic Choriomeningitis Virus (LCMV) as vaccine immunogens. We will prepare MEPCS-mRNA-LNP and LCMV-mRNA-LNP vaccines to ensure multiple conserved antigen expression as a single polypeptide unit by connecting each of antigenic peptide sequences via three different linker sequences. We will compare the efficiency of Gly-Gly-Ser (GGS) spacer, GGS plus A2 and GGS plus A2 and Furin linker sequences for their efficiency in antigenic expression.
- NIH Guidelines Section III-E, BSL 1
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22508657 - Weiner, David, ***DNA Delivery of monoclonal antibodies for prevention of antimicrobial resistant bacteria***
- This lab is studying the role of plasmid DNA encoded antibodies against antimicrobial resistant bacteria
- NIH Guidelines Section III-E, BSL 1
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22508658 - Montaner, Luis, ***Adeno associated virus***
- The objective of using AAV8 vectors is to express human cytokines in the NSG mouse inoculated with human CD34 stem cells in order to support immune differentiation of distinct human immune cell lineages. We will infect humanized

NSG mice with commercially obtained AAV8 expressing human cytokines. The viruses are ordered commercially; we use them directly as provided and only use in IACUC approved protocols.

- NIH Guidelines Section III-E, BSL 1
- All required trainings are complete.
- The Committee voted unanimously to approve the Registration.

22408634 Amendment 1– Claiborne, Daniel - **Engineering a Functional Cure for HIV**

- Change of Personnel and Change of location.
- Administratively Approved

22501643 Amendment 1 - Claiborne, Daniel - **Mouse models of autologous murine CAR T cell therapy**

- Change of Personnel and Change of location.
- Administratively Approved

22401615 Amendment 2 – Tempera, Italo - **Epigenetic Regulation of Epstein-Barr Virus Infection**

- Change of Personnel.
- Administratively Approved

22401616 Amendment 2 – Tempera, Italo - **Role of LMP1 in EBV infection**

- Change of Personnel.
- Administratively Approved

22403625 Amendment 1 – Shinde, Rahul - **The project aims to study the role of different tumor metabolites on PDAC tumor progression**

- Change of location and Additional Gene Inserts/Proteins to be expressed
- Full Committee Review and Approved

6.0 Discussion of Scishield Implementation Strategy/Review Protocols Roma Maraj-Owen

6.1 Roma Maraj-Owen discusses the Scishield Implementation process, and where we currently stand with the transition.

6.1 Roma Maraj-Owen reminds members who have not completed the Scishield training to do so immediately.

6.1 Denise DiFrancesco questions when the entire process would be transitioned.

6.1.3.1 Roma stated that the goal would be to start in the first quarter of 2026.

7.0 Open Discussion

7.1 Michelle Ho discusses the statement issued by the NIH on 9/9/2025.

7.1.1.1 Dr. Ami Patel questioned who all received the email notification and suggested that the admin distribute these emails as they arrive, to open the line of communication.

7.1 Denise DiFrancesco questions the frequency of how many times the IBC Committee must meet.

7.1 Denise DiFrancesco questions the process for returning information to the committee while submitting a Voting Sheet additional information request.

7.1.3.1 Dr. Ami Patel suggested that Denise could reach out to the IBC Chair, BSO, or the Director of Laboratory Operations and Environmental

Health and Safety for questions related to specific strands or recombinant DNA? Synthetic Nucleic Acid Molecules.

7.1.3.2 Roma Maraj-Owen added that their questioning and subsequent review could also instigate a full committee review.

7.1.3.3 Maurice Brandon interjected with a review of the administrative process for returned Voting Sheets requesting additional information.

8.0 The Meeting was adjourned at 11:29 AM

9.0 The next meeting will be December 10, 2025, from 11AM-12PM.

Chair or Designee Signature	**Date**
qingsheng li Digitally signed by qingsheng li Date: 2025.12.11 14:37:12 -05'00'	12/11/25