



Portal Innovations

Institutional Biosafety Internal Meeting Minutes

Topic:	July IBC Meeting
Date & Time:	25JUL25 @ 11:10am -12:00pm (CST)
Location:	Portal – Houston ([REDACTED])
Meeting Type	In person and Virtual Platform-Teams

A. IBC Roster

Name	Company	Title	Voting Status	Quorum
Joanna Krakowiak	Portal Innovations	Director of Lab and Scientific Operations-Houston- Biological Safety Officer	Voting	Present
Keilana Borja	Portal Innovations	Lab Operations Associate - Houston IBC Chairperson	Voting	Present
Elena Ramirez	Portal Innovations	Houston Scientific Representative/Expertise in Human Gene Transfer & Immunotherapy	Voting	Present
Sarah Wannemuehler	Triumvirate	EHS Consultant	Non-Voting	Present
Jennifer Hutchens	CBRE	Local Non-affiliated Member-Houston	Voting	Present
Nghi Nguyen	Texas A&M University	Local Non-affiliated Member - Houston	Voting	Present
Vilasack Thammavongsa	Immunartes	Chicago Scientific Representative/Expertise in Bacteria Pathogenesis	Voting	Present

B. Others in Attendance

Name	Company	Title	Voting Status	Quorum
Eric Smith	March Biosciences	Houston Scientific Representative/Expertise in CAR-T Cell Therapy Development	Non-Voting, Presenting	Present
John Mansueto	Portal Innovations	Portal Innovations Lab Operations Intern	Non-Voting	Present
Cooper Munro	Portal Innovations	Portal Innovations Lab Operations Intern	Non-Voting	Present
Emily Yee	Portal – Chicago	Lab Operations Associate; IBC Chairperson – Chicago	Non-Voting	Present



C. Minutes

Item	Topic
1.	<p>Welcome & Introduction (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Attendees were welcomed to the meeting and meeting participant role call was conductedAgenda for the meeting was reviewedNo review of previous meeting minutes or business as it is the first IBC meeting for Portal Innovations - Houston
2	<p>Role of the IBC (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Ensure compliance with NIH/CDC biological laboratory guidelinesMeet at least annually and submit IBC meeting minutesEnsure medical surveillance programs are in effect for users of recombinant and synthetic nucleic acidsReview and approve protocols for working with recombinant and synthetic nucleic acids, human source materials, infectious agents, and toxinsDiscuss issues relevant to improving safety of the work environment and the general public <p>Responsibilities of the IBC (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Reviewed the responsibilities, membership & registration requirements, stipulations, and the general cycle of the IBC
3	<p>Company Overview (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Overview of Portal Innovations from a high levelIncluded detailed information on the layout of the facility, lab designations, and facility mechanical systems pertinent to lab operations
4	<p>Operating Permits and Contract Status (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Information and status on permitting for the facilityInformation on current Operation contracts
5	<p>Biosafety Programs (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Reviewed current biosafety program
6	<p>Floor Plans and Emergency Equipment (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Facility layout and all locations of safety equipment (fire extinguishers, safety showers, eye washes, spill kit, and AED)
7	<p>Biomedical Waste Management (Sarah Wannemuehler)</p> <ul style="list-style-type: none">Discussed current biowaste management processes
8	<p>Project Registration for Review – March Biosciences (Eric Smith, Senior R&D Director- on behalf of March Biosciences)</p> <ul style="list-style-type: none">Brief overview of March Biosciences and their mission & visionProject Title: March Bio Research [New Registration 2025-001]



- Project Goal(s): To carry leading drug candidate ██████████ through clinical development by testing manufacturing methods.
- Principal Investigator: Maksim Mamonkin, PhD
- Project description and controls
 - Technical overview of the project
 - Performing work with primary human cells and healthy donor cell lines as well as cancer patient cells lines. Using gammaretroviral vectors and genome editing, they will be cloning and genetically modifying human cells. This is done by cloning the single-chain variable fragment into the retroviral vector with the ██████████ plasmid (BSL-2). The T-cells will then undergo transduction with the introduction of the engineered genetic material from the ██████████ vector (BSL-2) . Validation occurs by performing flow cytometry to determine the rate of expression on the modified T-cells (BSL-2).

Host Cell	Vector	Gene Insert	Gene Source	Description
HEK 293T/17	Peg-Pame/RDF/SFG backbone (SFG contains transgene)	Chimeric antigen receptor(s)	Human	Production of gammaretroviral vectors for use in stable integration of CAR(s) into primary human T cells
PG13	SFG backbone containing transgene	Chimeric antigen receptor(s)	Human	Production of gammaretroviral vectors for use in stable integration of CAR(s) into primary human T cells
293Vec-RD114	SFG backbone containing transgene	Chimeric antigen receptor(s)	Human	Production of gammaretroviral vectors for use in stable integration of CAR(s) into primary human T cells
293Vec-GalV	SFG backbone containing transgene	Chimeric antigen receptor(s)	Human	Production of gammaretroviral vectors for use in stable integration of CAR(s) into primary human T cells
Microorganism/Virus	Vector	Gene Insert	Gene Source	Description
E. coli (NEB Stable)	SFG, RDF, PegPam	various	Viral, human	Mini- and maxiprep of plasmids



	<ul style="list-style-type: none">▪ Inherent risk of using biological materials – can never be 100% certain there is no risk to working with these materials (bacteria, retrovirus, human samples)<ul style="list-style-type: none">• Will perform routine decontaminations of equipment and work tops after performing work with biological materials○ What BSL will be used? Have they considered BSL2-Plus?<ul style="list-style-type: none">▪ Work will be done under BSL2 and work does not require BSL2-Plus○ Is the retroviral work being done in a shared lab space?<ul style="list-style-type: none">▪ The lab is currently only used by March Biosciences . If another company moves in and equipment becomes a shared resource, further discussions and considerations will be made to ensure cross-contamination and biosafety controls.○ Registration form 6.5 is not very descriptive. We would like it to be more fleshed out. Included cleaning procedures for equipment (centrifuges)<ul style="list-style-type: none">▪ Needing more detail on the risks to health and safety associated with the research and materials being used <i>[provided by company]</i>○ Signage for dedicated equipment<ul style="list-style-type: none">▪ Discussed as an additional layer of communication to ensure contamination and process safety○ PPE requirements discussed – separate lab coats for bacterial work (wet lab)
10	<p>Vote:</p> <p>A motion was made to approve the registration pending the following changes or conditions to be met:</p> <p style="padding-left: 40px;">Section 6 Question 5 of project registration form to be expanded upon for further health and safety risk clarification</p> <p style="padding-left: 40px;">For = 6</p> <p style="padding-left: 40px;">Against = 0</p> <p style="padding-left: 40px;">Abstain = 0</p> <p>Conflict(s) of Interest: Eric Smith, Houston Scientific Representative</p>
11	Project Registration Notification – pending registration form updates
12	Review of Incidents and Inspections <ul style="list-style-type: none">• No incidents or inspections to be reviewed as of date of meeting - 25JUL25
13	Next Steps <ul style="list-style-type: none">• Await updated registration form• Internal discussion on equipment signage for private use



D. Post-meeting updates

1	<p>Portal Innovations update:</p> <ul style="list-style-type: none">• Signage for centrifuge posted to be used only with BSC used by March Biosciences• Modified PPE Protocol for Bacteria Room – A distinct-colored disposable lab coat will be designated exclusively for this room to enable easy monitoring and ensure proper use. PPE worn in the Bacteria Room must remain in the room and may not be used elsewhere. Portal Innovations will supply 70% alcohol and gloves within the room and dedicated rack will be installed for the permanent storage of members' consumables to minimize the transfer of materials in and out.
2	<p>March Biosciences update:</p> <ul style="list-style-type: none">• On 8/10/2025, an updated EHS form was provided with an expanded Section 6.5. The safety risks associated with the research were outlined, along with the engineering controls and PPE measures in place to minimize exposure. The decontamination protocol was specified, and waste disposal procedures were detailed.
3	<p>Final decision for IBC</p> <ul style="list-style-type: none">• Approved