IBC Meeting Minutes

Meeting Minutes
6/13/2025 9:30 AM

Voting Members Present
Sasha Azar, PhD Vice-Chair
Jillian Chahal,
Edward Graviss, PhD, MPH
Daniel Kiss, PhD
Joan Nichols, PhD
Jiangyong Shao,
Tamara Steele,
Nagendran Tharmalingam, PhD
Anjana Tiwari, PhD
Vicente Zuno,

Other Non-Voting Attendees:
Malissa Mayer-Diaz
Prince Agyapong
Shane Wilson
Perla J. Rodriguez

Voting Members Absent:
Francesca Taraballi, PhD
Sachin Thakkar, PhD
Biana Godin, PhD Chair
Chas Gray, RPh

Non-Voting Members Present:

Call to Order:

The Institutional Biosafety Committee met via Microsoft Teams on June 13, 2025, 9:29 am. The ad hoc meeting was called to order at 9:29 am with 10 members present. 9 members are required to meet quorum.

Reports:

- None

Conflict of Interest:
Committee members were reminded by the IBC Chair to recuse themselves in the event of any conflicts of interest.

Old Business:

- None

New Business:

- None

Minutes Review:

- None

Agenda Items:

IBC NEW APPLICATIONS

IBC00002327
Expanded Access Program for Obe-cel Out-of-specification in Adults with Acute Lymphoblastic Leukemia
Principal Investigator: Carlos Ramos

- **Summary**: Dr. Carlos Ramos and his team addressed the IBC's concerns during the 6/5/2025 meeting. As the application had been previously tabled, they requested an ad hoc meeting for expedited review. The IBC submission is for a single-arm, open-label, multi-center Expanded Access Program (EAP) for Obecabtagene Autoleucel (obe-cel), a CAR T-cell therapy for adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL). The EAP will provide access to out-of-specification obe-cel products that, while not meeting full commercial release criteria, are deemed safe and acceptable by both Autolus and the treating physician. The program will collect safety data for 45 days post-infusion, focusing on adverse events such as CRS, ICANS, infections, and secondary malignancies. Patients must be prescribed commercial obe-cel prior to leukapheresis and will be consented after notification of product specification status. No additional clinical visits are required, and product delivery will be managed by the sponsor. The risk of exposure to personnel is low- utilizing replication deficient viral vectors to produce the CAR-T cells. Transport of the therapeutic to the clinical patient care area within the hospital follows the proper packaging and labeling to prevent a spill or release. Furthermore, clinical trials team administering the CAR-T cells to patients are wearing the appropriate PPE to mitigate the risk of exposure to the drug or bloodborne pathogens and have been trained to prevent accidental needlestick injury. Shedding of retroviral vectors from the patients is low, due to the replication deficient characteristics of the vectors.

- **Training**: All staff members are currently up to date with their training.
- **Applicable NIH Guidelines**: Section III-C-1
- **Containing Conditions to be implemented**: BSL2
- **The motion to approve was seconded and passed. The IBC subsequently approved the study.**

Motion: Approved

- Yes Votes: 10
- No Votes: 0
- Abstained: 0

Adjournment:

- The meeting adjourned at 9:35 am.
