

BIOSAFETY COMMITTEE MEETING

MINUTES

The Watertown BioSafety Committee has scheduled a REMOTE ZOOM meeting on Thursday May 6, 2021 at 7:00 pm

PRESENT: Heather McManus PhD, Chairperson, Bradford M. Parsons Committee Member, Deborah L. Mc Ewan PhD Committee Member, Larry Ramdin, Director of Public Health

Staff: Maureen Foley, Head Clerk

In attendance Jim O'Connell, Maureen Caligiuri, Caroline Evarts, Will Adams, Michael Vaine, Neil Kelly, George Kenty, Mark Murphy, Cory Martin, Michael Tchen, JF Blaine, Anna Alves, Rachel Shilling, Jonathan Gel, Micah Zajic, James Doubertey, Rae Moor, Rob Derosier, Howard Bernstein, Mattias, Duane Burnett

CALL TO ORDER: Dr. McManus called the meeting to order 7:02 pm

Minutes

Tabled Minutes for December 3, 2020, January 7, 2021, February 4, 2021, March 4, 2021 to a later date and Approved Minutes for April 1, 2021. ^[SEP]Motions granted (Ramdin, Parsons) 4-0 ^[SEP]All in favor.

Public Comment

No Public comments

Forma Therapeutics – 500 Arsenal Way

Jim O'Connell, Director of Operations and Environmental Health & Safety gave a short presentation of the company's activities. ^[SEP]Brad Parsons stated the application was thorough. Brad questioned the process of flammable reactions and what it entails.

Deborah L. Mc Ewan was pleased with the protocols in place and the expertise with the use of the lentivirous. Dr. McEwan inquired about the move from 500 Arsenal to 300 North Beacon and how the experiments, agents and materials are being transferred in August 2021. Forma will transport materials in frozen state.

Larry Ramdin indicated the bleach concentration on the application was incomplete. ^[SEP]Dr. McManus stated the application was thorough and easy to navigate. Also, the lentivirus protocols were thorough and well thought out.

A motion was made to recommend approval of the application to the Board of Health. Motions granted (Ramdin, Parsons) 4-0. ^[SEP]All in favor.

Forma Therapeutics – 300 North Beacon Street

Brad Parsons asked about where the hazardous waste and the size of the containers that will be stored in the new facility. ^[SEP]Larry Ramdin asked about where the lab is located and if the waste is located in the first floor office space area. Also in EAP, when spills happen, the Board of Health must be notified within 24 hours.

Brad Parsons asked how the hazardous waste is transported from the lab to the first floor storage room.

A motion was made to recommend approval of the application to the Board of Health with the following conditions:

1. Larger floor plan^[1]2. More information on the decontamination concentrations^[1]3. Notification of spills to the Board of Health

Motions granted (Ramdin, Parsons) 4-0. All in favor.

Arkuda Therapeutics

Duane Burnett, Sr. Vice President gave a short presentation of the company's activities.^[1]JF Blaine, Vice President clarified the materials and agents used at Arkuda.^[1]

Dr. McEwan stated she appreciated the listing of cell lines used but that The security protocols were not included in the application.

Larry Ramdin stated to indicate the bleach concentration on the application and insure the correct solution rate. Per Larry, lab decomposition for lentivirus is 10:1 =500 parts/mill. The certificate of insurance does not name the Town of Watertown. The IBC presentation was in the application not the minutes.

Dr. McManus was concerned about the mixed-use building in terms of access, freight and waste storage. She stated Arkuda needs an SOP when utilizing lentivirus. NIH has a risk assessment plus an occupational risk for the lentivirus and there is no reference of lentivirus as a BSL-2 material in the application.^[1]

Brad Parsons stated there are too many requirements missing in the application. Dr. McEwan agreed. Larry Ramdin stated BOH will require these details in order to approve. Larry wants to table this application until June's meeting. Dr. McManus agrees also.

A motion was made to recommend tabling Arkuda's application until next month's meeting:

Motions granted (Ramdin, Parsons) 4-0. Role Call

SQZ Biotechnologies Company

Deborah L. Mc Ewan recused herself from this discussion.^[1]

Howard Bernstein, Chief Scientific Officer gave a short presentation of the company's^[1]activities.

Larry Ramdin stated the application was easy to read.^[1]Larry Ramdin indicated the bleach concentration must be on the application and new solution must be prepared daily.

Brad Parsons stated the EAP should be updated to accommodate spills, after hours work and weekends. Brad stated the application was well prepared.

Dr. McManus stated the application was easy to navigated and SQZ has a well secured system in place to protect the building and staff. The IBC notes were thorough and detailed. A motion was made to recommend approval of the application to the Board of Health with the following conditions:

1. SOPs for the lentivirus^[1]2. Updated protocols referenced in IBC meeting minutes^[1]3. Shelf life of bleach solution and change the protocols to prepare bleach solution daily

Motions granted (Parsons, Ramdin) 4-0. All in favor.

Riparian Pharmaceuticals

William Adams, CEO gave a short presentation of the company's activities.

Dr. McManus stated Riparian submitted a Registration for 2021. After reviewing the application and contacted the NIH, Office of Science & Policy for clarification, Dr. McManus feels Riparian work (the insertion of lentivirus vectors carrying various pay-loads into tissue culture) is not exempt from the NIH Guidelines and requires permitting in Watertown. This does not mean the company stops any work. Riparian must come into compliance by July 1, 2021. Dr. Mc Ewan stated where there is lentivirus particles and genecopoeia primary human cells, this facility meets the standard for permitting in Watertown.

Additional Business

Dr. McManus stated as more labs come to the community and biosafety starts to branch out, the committee needs to clarify low risk vs. permitting. The committee agreed to have a special meeting on May 20th to determine what lab qualifications require a registration or a permit.

Adjourn: Ramdin recommended Adjourn, Parsons 2nd 9:32 PM

All in favor. Respectfully submitted: Larry Ramdin, Director of Public Health