Biosafety Committee Meeting

Thursday, December 7, 2023 at 7:00 PM
Remote Participation Only

Agenda

Pursuant to Chapter 2 of the Acts of 2023, the meeting and public hearing will be conducted with remote opportunities for participation. Remote participation and access methods include:

ACCESS INFORMATION:

A. This meeting will be held on Thursday, December 7, 2023 at 7:00PM. Location: Remote Participation Only

B. The Public may join the virtual meeting online: https://watertown-ma.zoom.us/j/88536131731?pwd=bEU1d3JLa0JrU25ZTXpTdUpBUEI5UT09

C. Public may join the virtual meeting audio only by phone: (877) 853-5257 or (888) 475-4499 (Toll Free) and enter Webinar ID: 885 3613 1731

D. Public may comment through email: ameyers@watertown-ma.gov

E. Please Visit the Biosafety Committee Website here: https://www.watertown-ma.gov/398/Bio-Safety-Committee-Biotechnology

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1. Call Meeeting to Order
2. Acceptance of Minutes
   A. Approval of draft minutes of November 2, 2023
3. Public Comment
4. Amendment applications for:
   A. Mariana Oncology – 100 Forge Road
5. Permit applications for:
   A. Parallel Squared Technology Institute – 490 Arsenal Way #110
6. Additional Business
7. Items that could not be anticipated before meeting
8. Future Meetings
9. Adjourn

Biosafety Committee Meeting

Minutes

The Watertown BioSafety Committee has scheduled a REMOTE ZOOM MEETING on Thursday November 2nd, 2023.

PRESENT:
Brad Parsons, Deb McEwan, Ralph Mele, Mia Lieberman, Tim Maguire

In Attendance:
Andrew Thomas, Bryan Iwanicki, Cameron Blair, Cysteine (Matchpoint conference room), David Dobrosky, David Keane, Getzabel Guevera, Jack Jezard (Safety Partners), James Holland, Luke Amirauit, Mohammed Hanna (Transition Bio), Mutya Cruz, Roman Bogorad (Souffle Tx), Sarah Mullinax, Sibhon, Al Nadar (Matchpoint Therapeutics), Christopher Hren, Linda Scott

CALL TO ORDER: Brad Parsons called the meeting to order at 7:03 PM EST

Minutes
Minutes Approved for October 5th, 2023

- Acceptance as written
- Brad – proposed to accept minutes
- Ralph – second
- All approved

Public Comment

- Linda Scott
  - Labs are different emissions standards then manufacturing
  - Sent the safety committee an email
  - To be handled by Board of Health
  - Question on a chemical emission
  - Asked who's prevue covers / decides emissions standards

Amendment Applications

<u>Dyno – 343 Arsenal</u>

- Documentation was as thorough as an application
- No questions from Biosafety committee
- Do not need to go in front of board

<u>Souffle Therapeutics (BTP-190) – 85 Walnut</u>

- Documentation was as thorough as an application
- Brad Parsons Questions to Cameron Blair, Roman

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    - Is there a change in scope of research – no the R&D scope is the same
    - Floorplan vivarium- coming later (3/2024) as an amendment
        - Disaster plan
        - IBC minutes on vivarium planning
    - Request higher resolution floorplans
    - Is there waste being generated on the 1st floor
        - Cameron – use 1st floor zone as overflow, or satellite accumulation for waste removal
    - Movement of chemical waste between floors using elevators – use best practices
    - Cameron – main accumulation area is above ground, on the 2nd floor
    - Occupancy date 2/12
- Ralph Melee questions
    - Category 1 and 2?
        - Cameron – all category 1
    - Providing updated chemical plan
- Deb McEwan questions
    - Please update screening document that NHP samples are from a CRO
- 155 Arlington will be out of the facility by 3/2024
    - Commercial transport of material between sites
- No need for Board of Health review for the move to 212
- Board of Health will review for the vivarium
- Propose – amendments of floors plans, sample screening

<u>Transition Bio – 85 Walnut</u>

- Update suite number to 110; same space
- Ralph asked if any of the space
    - Getzabel said the floor plans cover all of the space
- Getzabel submitted chemical hygiene plan in the original application
- Deb asked if there was an IBC meeting for the move
    - Getzabel said there was not one, but one will come up in 1/2024
    - Mia said if the scope, and procedures are not changing, then an IBC meeting is not needed
- Renewal paper work is needed in December

Permit Applications :

<u>Matchpoint therapeutics – 57 Coolidge</u>

- Presentation – Al Nadar (SD Research)
    - rDNA permit application
    - Wei Li- VP at Matchpoint
    - Cristopher Ren – Corp Development
    - Currently in Cambridge (1 Kendall)
    - James – SD Finance

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    - Sarah – Consultant from Safety Partners
    - Foci – covalent small molecule for serious immune disease
    - Company Founded in 2021
    - 28,000 Sq FT50/50 labs / offices
    - 2 tissue culture suites (200 sq ft) - BSL-2
    - Whole facility is badge access
    - Initial lab entry is to an enclosed area for donning PPE prior to entering active lab space
    - Recombinant DNA
        - Commercially available transfected cell lines
        - Human primary cells to test small molecule on protein binding and cell update / clearance
        - In the event they cannot find a line they generate one
            - Only buy 4th generation LVV
            - Volume < 100mL
    - Use whole blood; cells derived from whole blood
    - No toxins are used
    - Last IBC – 8/2023
- Brad Question
    - Floor plan – is there negative pressure in [ ] room if both doors are open
    - What types of gas
        - Argon in the future
- Mia questions
    - IBC minutes and agents list need to indicate whole human blood
    - Is there a vendor?
        - Yes its commercially screened
    - Deb
        - What cells will be separated from whole blood
            - PBMCs
    - Ralph
        - Floorplan
            - BSL2 in corner outside of area
                - Storage
- Proposed updates
    - Agent list
    - Floor plan as submitted with different color for storage
- Motion to submit to board of health with updated agent list – Mia; Deb second
    - All vote to approve
    - Next Board of Health is 11/15
    - Maureen will send details

Additional business

- Nov 15 is the Board of Health meeting and the Biosafety committee is on the agenda

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- Discuss when they Board needs to see amendments

Items that could not be anticipated

- Jack at Safety Partners Asked how Forma Therapeutics (Now Novo Nordisk) should be named as the entity, for renewal, and if anything in the renewal needs to be highlighted
    - Pest control update with new name
    - Name update on all documents
    - Certifications have to have new names
    - Liability has to have new name
- Explora is now Charles River and will need to update documents

Next Meeting

The next meeting will be Thursday, Dec 7, 2023, at 7:00 PM EST

Adjourn

Adjourned at 8:21 PM EST

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