

WBSC 3/4/21 Minutes

1. Dr. McManus Called the meeting to order at 7:09 PM
2. Dr. McManus gave a brief overview of the permitting/registration process.
3. Permit Applications
 - Werewolf Therapeutics
 - Cynthia Seidel-Dugan, Ph.D. (Chief Scientific Officer), gave an overview of the company's work.
 - Mr. Parsons asked if the chemical hygiene plan and chemical inventory will be unique to the Watertown site and if chemicals would be moved from Cambridge to Watertown. Dr. Seidel-Dugan stated that the hygiene plan and inventory are specific to the Watertown site and that chemicals will be ordered for the Watertown site, not moved from Cambridge. She also stated that upper management sits on the safety committee. Mr. Parsons raised concerns over the Hydrogenation Equipment reference in the Chemical Hygiene Plan (appendix 13 pg. 89) – as this requires additional permitting and oversight. Dr. Seidel-Dugan stated they are not doing hydrogenation and that the reference would be removed from the manual.
 - Dr. McEwan asked for further clarity on the lentiviral insert approval process and safety protocols. Dr. Seidel-Dugan stated that oncogenic inserts will not be used and mentioned double gloving, disposable lab coat covers, and appropriate signage. Dr. McEwan asked that Werewolf's Watertown IBC meet and finalize minutes before permit approval.
 - Lt. David Meagher (WFD) asked to set up a walkthrough for the Fire Department, mentioned that when a company has key access it is essential for the Fire Department to have contact information for a safety officer, and echoed Mr. Parsons concerns about the mention of Hydrogenation in the CHP. He asked that the Fire Department's contact information be corrected in the Emergency Response Plan.
 - Mr. Parsons moved that "The WBSC recommend the Board of Health approve *Werewolf's* rDNA permit application once the following conditions are met; removal of the reference to hydrogenation in Appendix 13 of the Chemical Hygiene Plan, correction of the Watertown Fire Department contact information in the Emergency Response Plan and associated material, and that they provide the WBSC with finalized minutes from an initial IBC meeting". **The motion was seconded and passed 5-0**
 - ALS Therapy Development Institute (ALS TDI)
 - Fernando Vieira (CEO), Kyle Denton (Senior Scientist), and Ken Thompson (Biosafety Officer) gave an overview of the company and its work.
 - Dr. McEwen asked that the IBC meet prior to permit approval and supply the WBSC with finalized minutes.
 - If not applicable, Mr. Parsons asked that Hydrogenation be removed from the biosafety manual and asked for clarification on the compressed gases used.
 - Lt. David asked to set up a walkthrough for the Fire Department and asked that Fire Department's contact information be corrected in the permit application material.

- Dr. McManus asked if patient samples are screened for COVID; applicants responded that they are currently only using pre-COVID samples.
- Mr. Parsons moved that "The WBSC recommend the Board of Health approve *ALS Therapy Development Institute's* rDNA permit application once the following conditions are met; removal of the reference to hydrogenation in Appendix 13 of the Chemical Hygiene Plan, correction of Watertown Fire Department contact information in the Emergency Response Plan and associated material, and that they provide the WBSC with finalized minutes from an initial IBC meeting". **The motion was seconded and passed 5-0**
- RootPath
 - Ely Porter, Vice President of R&D, gave a company overview.
 - WBSC asked the same questions asked of previous applicants.
 - Mr. Ramdin moved that "The WBSC recommend the Board of Health approve *RootPath's* rDNA permit application once the following conditions are met; removal of the reference to hydrogenation in Appendix 13 of the Chemical Hygiene Plan, correction of Fire Department contact information in the Emergency Response Plan and associated material, and that they provide the WBSC with finalized minutes from an initial IBC meeting". **The motion was seconded and passed 5-0**
- Prolacta
 - Gregory McKenzie, Vice President, Product Innovation, gave an overview of the work.
 - WBSC voted 5-0 to approve Low-Risk Facility registration for BSL-1 work.
 - WBSC discussed permit application for BSL2
 - Similar questions and concerns asked of other applicants were discussed.
 - Dr. McManus asked for clarification on if strains that are patient isolates are used, if strains will be isolated from patient fecal samples, and if all co-culture work will be destructive (i.e., disposed of the following work).
 - Mr. Ramdin moved that "The WBSC recommend the Board of Health approve *Prolacta's* rDNA permit application once the following conditions are met; correction of Watertown Fire Department contact information in the Emergency Response Plan and similar material, editing of the Chemical Hazardous waste protocol to read "if created waste will be" instead of "is", and that they provide the WBSC with finalized minutes from an initial IBC for meeting ". **The motion was seconded and passed 5-0**

4. Chair Updates

- Dr. McManus mentioned having Steve Magoon from Watertown Community Development and Planning come to a WBSC meeting to coordinate the WBSC's work with new development in town. Mr. Ramdin suggested that Mr. Magoon speak to the committee ASAP as several project planning meetings are underway for new developments. Mr. Parsons agreed that a discussion with Mr. Magoon should be prioritized.
- Dr. McManus shared with the committee that she had spoken with Sam Lipson of the Cambridge Biosafety committee and that he is excited to see the WBSC up and running.

Mr. Lipson offered to come to a future WBSC meeting to discuss the process in Cambridge as well as emerging technologies/operations etc.

- Mr. Ramdin informed the committee that a letter to companies has been created and will go out soon, as will a press release encouraging companies to submit applications. Mr. Ramdin mentioned that the Health Department is very busy with vaccination clinics and other COVID-related matters.

5. Discussion on items for clarification on FAQ and other permitting concerns

- Dr. McManus mentioned that three applicants had misidentified themselves as Low-Risk Facilities by incorrectly stating their rDNA work is exempt from NIH Guidelines when it is not. The WBSC discussed ways to prevent future occurrences.
- It was discussed that the FAQ needs to be updated to remove the requirement for a site visit during the permit process (due to COVID). Mr. Ramdin emphasized that companies are still subject to inspection by the Health Department at any time.
- It was reiterated that companies need to have an initial IBC meeting and provide the WBSC with the minutes prior to coming before the WBSC.

Adjourned