



CITY OF  
WATERTOWN  
BOARD OF HEALTH

Administration Building  
149 Main Street  
Watertown, MA 02472  
[www.watertown-ma.gov](http://www.watertown-ma.gov)

Barbara Beck PhD  
Richard Arnold FNP BC

**BIOSAFETY COMMITTEE MEETING  
THURSDAY, MARCH 3, 2022 AT 7:00 PM  
AGENDA**

**Thursday March 3, 2022 at 7:00 PM**  
**The Watertown Board of Health has scheduled a REMOTE ZOOM meeting on**

Join Zoom Meeting on March 3, 2022 07:00 PM  
<https://watertown-ma.zoom.us/j/88536131731?pwd=bEU1d3JLa0JrU25ZTXpTdUpBUEl5UT09>  
Meeting ID: 885 3613 1731

**The committee will accept written comments in addition to the comments in the public comment period. These comments can be sent to [lraindin@watertown-ma.gov](mailto:lraindin@watertown-ma.gov)**

1. Call Meeting to Order
2. Acceptance of Minutes
  - A. Approval of Minutes of February 3, 2022
3. Public Comment (Open to the public to offer input on Biosafety matters matters)
4. Permit applications for:
  - A. Myro Therapeutics, Inc. - 155 Arlington Street
  - B. Landmark Bio, PBLLC - 300 North Beacon Street
5. Procedure for Permit Amendments (ie. A company moves within the City of Watertown)
  - A. Attachment: WBSC Procedures Amendments DRAFT 3-3-22
6. Update on edits to the presentation discussed at the 2-3-2022 meeting
  - A. Attachment: WBSC PPT Update March Meeting.ppt
7. Discuss Annual Restructuring of the WBSC
8. Items that were not anticipated before publication of this agenda
9. Adjourn

# BIOSAFETY COMMITTEE MEETING

## MINUTES

**The Watertown BioSafety Committee has scheduled a REMOTE ZOOM meeting on  
Thursday February 3, 2022 at 7:00 pm**

**PRESENT:** Heather McManus, Chair, Bradford M. Parsons Committee Member, Dr, Deborah McEwan, Deanna Mazina, Chief Health Officer, Maureen Foley, Staff

Consultant: Mia Tova Lieberman  
In attendance Rae Moore

**CALL TO ORDER:** Heather McManus called the meeting to order 7:02 pm

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### Minutes

Minutes approvals for January 6, 2021  
(McEwan, Parsons)  
Roll Call

### Public Comment

No Public Comment

### New Business: Discussion of the WBSC's work so far, and recommendations moving forward.

The committee discussed the draft of a presentation (proposed at the 1/6/21 WBSC meeting) to be presented to the Board of Health and City Council. (Attach File: WBSC\_Summary\_Draft\_PowerPoint.pdf).

WBSC wants to indicate the number of companies permitted and registered throughout the period. Some City Council members have informally requested the committee make a presentation at a council meeting and/or Council Subcommittee meeting. WBSC wants to identify the gaps in lab activities that fall outside of the WBSC purview. Dr. Lieberman wants to identify the chemical concerns. Mr. Parsons stated 500 grams of cyanide is not regulated by any entity and other toxins used in research that do not fall under Flammable Storage Permits. There are chemical hazards that may not currently be reported to the Fire or the Health Dept under an existing City permitting structure. Buildings with multi tenants using class 1 chemical lab should require an inventory. Those particulars do not fall under the responsibilities of the WBSC.

Dr. McManus stated the WBSC has information and perspective she would like to see conveyed to the City Council and the Planning Department.

Mr. Parsons stated the WBSC should determine the qualifications for inspections. Dr. McManus stated inspections, fines and violations are Health Department responsibilities. WBSC can conduct site visits to inform labs of procedures and policies.

Dr. McEwan is concerned about the potential for a new agent to be developed out of a university that has not previously been regulated.

Dr. McManus raised the need for another Chair election. She has been Chair for a year and would like others to have a chance to Chair. It was suggested that the WBSC should set an election policy/procedure. There was discussion about the frequency of rotation of the WBSC Chairperson. It was noted that the 5<sup>th</sup> member of WBSC does not attend meetings or participate in application review. To elect a new chairperson all members should be present.

The WBSC discussed whether permitting BSL 3 level labs in the City is practical due to lack of capacity. Prohibition of BSL3 labs would require amending the regulations.

WBSC would like to know how the Fire Department plays into the application process going forward.

**Adjourn:**

8:27 PM

Respectfully submitted: Larry Ramdin, Director of Public Health

Procedures and Protocols of the Watertown Biosafety Committee  
Proposed Additions to existing policies (March, 3rd 2022)

(Section 1-4 discuss the applicability of Watertown's Biotechnology Regulation to different types of Life Science Work and were approved by the WBSC on Nov. 4, 2021)

Section 5 – Permit Amendments (Proposed for review at WBSC 3/3/22 meeting)

**1. An increase in BSL at an existing site.**

1. An increase in BSL-1 to BSL-2 requires.....
2. An increase from BSL-1/BSL-2 to BSL-3 requires a full permit application, fee, and review by the WBSC. Before permit issuance, a third-party inspector must inspect and approve the new BSL-3 suite.

**2. Use of a new Select Agent**

1. The use of a new select agent requires a full permit application and fee and review by the WBSC.
2. If a company has already been approved for use of a Select Agent, and wish to introduce a new select agent..... (TBD)

**3. Change in address**

1. Relocation of a company within the same building requires IBC review and submission of the resulting minutes to the Health Department.
  1. Exception: Relocation of a BSL-3 containment suite within the same building requires a full permit application, fee, and review by the WBSC. Before permit issuance, a third-party inspector must inspect and approve the new BSL-3 suite.
2. Relocation of a company to a new street address in Watertown requires a new permit, complete with a fee, application materials, and an IBC meeting specific to the new location.
  1. If the scope of company's work remains the same, the company's application will be reviewed by the Health Department. The Health Department will pay particular attention to the new site's security, waste management, and floor plans when determining if the application requires full review by the WBSC. If not, the application will be ??? granted by the Health Dept. or go before the BOH to be granted???
  2. The Health Department Research Consultant will review applications that have a change in address and a significant change in the scope of work (i.e., new agents and protocols). A review of the IBC minutes and the accompanying protocols will determine if the new scope of work requires full review by the WBSC. If not, the application will be ??? granted by the Health Dept. or go before the BOH to be granted???
  3. Companies moving to a new address and proposing an increase in the Permits BSL and/or the use of a new Select Agent will require full review by the WBSC.
  4. Relocation of BSL-3 permit to a new street address within Watertown requires coordination with and full review by the WBSC. Before permit issuance, a third-party inspector must inspect and approve the new BSL-3 suite.

**Section 6 – Comprehensive policy for Incubator Spaces (TBD)**

**Section 7 – Site Visit Policy and Procedure (TBD)**

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## Overview

- Watertown Biotechnology Regulation
  - NIH Guidelines, rDNA, and biosafety levels
  - What the regulation does
- Watertown Biosafety Committee
  - Members
  - Permitting Process
  - Summary of work
- Looking to the Future



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## Watertown Biotechnology Regulation

- Adopted by the BOH in November of 2019
- Effective date of July 1<sup>st</sup> 2020
  - Existing companies had a year to come into compliance
- First permit application Nov 2020
- Based on similar regulations in neighboring municipalities
- Requires applicable companies to adhere to the NIH Guidelines



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## NIH Guidelines for Research involving rDNA molecules

- Specify best practices for constructing and handling:
  - Recombinant DNA (rDNA/sDNA molecules)
  - Organism and viruses containing rRNA/sDNA molecules
- Founding principles
  - Responsible conduct of research
  - Development of a transparent biosafety governance framework



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## What is rDNA and sDNA?

- rDNA
  - Molecules constructed outside of living cells by joining natural or synthetic DNA segments
- sDNA
  - Synthetic DNA segments
- Examples of work using rDNA/sDNA
  - Studying genes and genomes
  - Viral or bacterial vectors
  - Constructing modified cell lines
  - Genetically modified plants, animals, and insects
  - Human Gene Transfer



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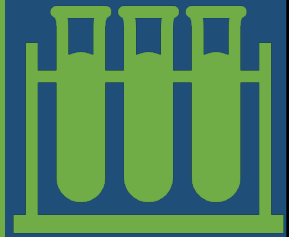
|                                                                                 |                                                                                                                                                                                                                                                                                                                                                              |                          |                                    |
|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------------------------|
| <b>BSL1</b><br>                                                                 | <b>BSL1</b><br>① controlled access<br>② hand washing sink<br>③ sharp hazards warning policy<br>④ personal protective equipment<br>⑤ laboratory bench<br>⑥ autoclave                                                                                                                                                                                          | <b>BSL -1 Risk Level</b> | Worker: Low<br>Community: Low      |
| <b>BSL2</b><br>                                                                 | <b>BSL2</b><br>① controlled access<br>② hand washing sink<br>③ sharp hazards warning policy<br>④ physical containment device<br>⑤ personal protective equipment<br>⑥ laboratory bench<br>⑦ autoclave                                                                                                                                                         | <b>BSL -2 Risk Level</b> | Worker: Moderate<br>Community: Low |
| <b>BSL3 (WITH RISK-BASED ENHANCEMENTS)</b><br>AIR TIGHT (WHEN DISINFECTING)<br> | <b>BSL3</b><br>① self-closing double-door access<br>② controlled access<br>③ personal shower out<br>④ sharp hazards warning policy<br>⑤ hand washing sink<br>⑥ sealed penetrations<br>⑦ physical containment device<br>⑧ powered air purifying respirator<br>⑨ laboratory bench<br>⑩ autoclave<br>⑪ exhaust HEPA filter<br>⑫ effluent decontamination system | <b>BSL -3 Risk Level</b> | Worker: High<br>Community: Low     |



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## Biotechnology Regulation

- Prohibits RG4/BSL-4 work in Watertown
- BSL-3 must have an annual independent third party inspection of the facility (**currently no BSL-3 labs**)
- Most rDNA/sDNA work requires permit
- Work with BSL-2 pathogens requires a permit
- Permitted companies must seek a permit amendment for new BSL-3 work and/or work with select agents
- "Low-risk" life science labs can register with the health dept in place of permitting



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## Biotechnology Regulation

- Forms a Watertown Biosafety Committee to advise the BOH on permit applications
- Requires permitted companies to adhere to the NIH guidelines
- Permitted companies must have an internal Institutional Biosafety Committee with at least one Community Member
  - Someone who lives or works in Watertown; or
  - Someone who lives in Newton, Belmont, Waltham, West Cambridge or Allston/Brighton



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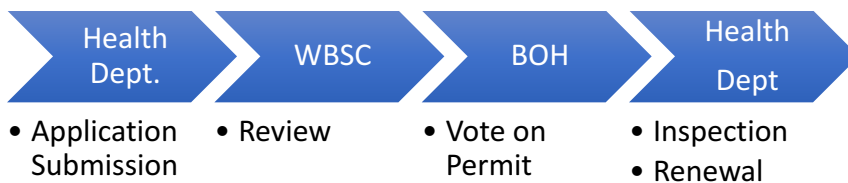
## Watertown Biosafety Committee

- Make-up
  - Representative of the Health Department (Larry Ramdin)
  - BOH Chair of their designee (Dr. Heather McManus)
  - Representative of the Fire Department (Lt.)
  - Two Watertown Residents with Life Science experience
    - Dr. Deb McEwan (Research Scientist)
    - Brad Parsons (EHS Professional)
- Meets monthly to review permits
  - 1<sup>st</sup> Thursday of the month
- Determines policy and procedures for the WBSC



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## Permitting Process



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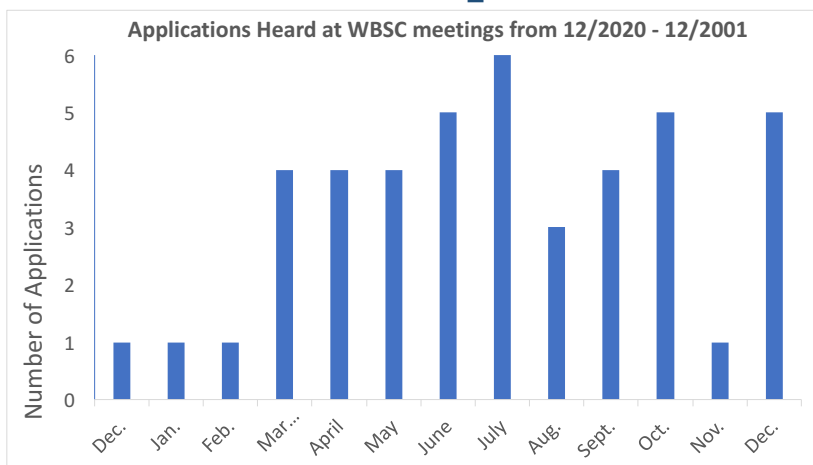
## Permit Application Material

- An overview of work conducted and techniques used
- A list of biologic organisms used, their specific hazards and needed decontamination or monitoring
- Plot plan of the facility and description of site security
- Waste management plan
- Proof of Pest Control
- Occupational Health Services
- Companies Safety Manuals (Biosafety, Chemical Hygiene and Emergency Response Plan)
- Proof of Liability Insurance
- Documentation of an active IBC
- Detailed description of annual safety training



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## 2020/2021 permits



Permits Issued: 38  
Registrations Granted: 5

Existing Companies: 24  
New Companies: 22

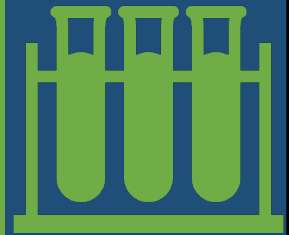


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## Life Science Companies in Watertown

| Type                                                  | Number of Companies |
|-------------------------------------------------------|---------------------|
| Life Science companies requiring a Biotech. Permit    | 41                  |
| Life Science companies requiring only Registration    | 5                   |
| "Life Science" not covered by the Biotech. Regulation | 24                  |
| <b>Total</b>                                          | <b>70</b>           |

| Type (Not Covered)                             | Number of Companies |
|------------------------------------------------|---------------------|
| Clinical Lab                                   | 2                   |
| Lab Equipment                                  | 2                   |
| Medical Device                                 | 6                   |
| Pharmaceutical without rDNA or BSL-2 pathogens | 9                   |
| Makes Reagents                                 | 2                   |
| Other                                          | 3                   |



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## Looking to the Future



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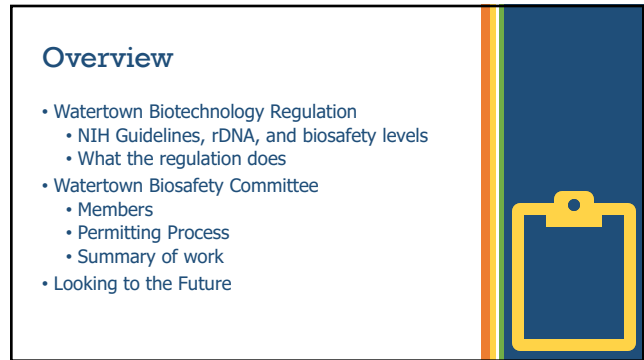
## What are Biosafety Levels

| 4 RISK CLASSIFICATIONS OF INFECTIOUS MATERIAL                                                                                                  |            |           |                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------|-------------------------------------------------------------------------------|
| Risk Group                                                                                                                                     | Individual | Community | Examples                                                                      |
| <b>1</b><br><b>(lowest)</b><br>Basic Laboratory, clean open bench, no BSC needed (unlikely to cause disease in healthy workers/animals/plants) | Low        | Low       | -non-infectious bacteria<br>-E. coli<br>-Lactobacillus spp.                   |
| <b>2</b><br>Biological safety cabinet needed<br>Pathogens spread via ingestion, inoculation and mucous membrane routes                         | Moderate   | Low       | -Influenza virus<br>-Herpes simplex<br>-Hepatitis (A, B, C, D, E)<br>-Tetanus |
| <b>3</b><br>Pathogen transmitted by aerosols<br>HEPA filtration required, respiratory protection                                               | High       | Low       | -Hepatitis (some C's)<br>-West Nile<br>-Anthrax<br>-TB                        |
| <b>4</b><br><b>(highest)</b><br>serious human disease that may not be treatable, easily transmitted<br>self-contained lab                      | High       | High      | -Ebola virus<br>-Herpes B                                                     |

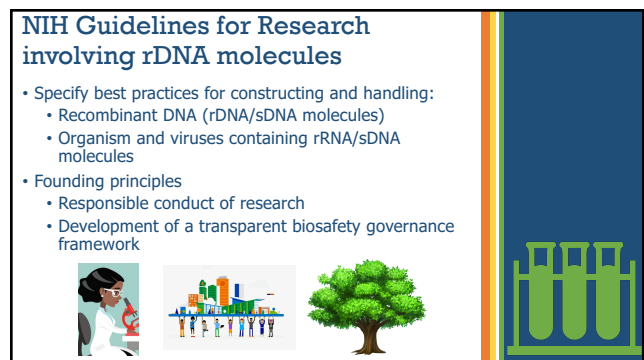


2 New slides since Jan WBSC Meeting. Outlined in red boxes

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## DRAFT

## What is rDNA and sDNA?

- rDNA
  - Molecules constructed outside of living cells by joining natural or synthetic DNA segments
- sDNA
  - Synthetic DNA segments
- Examples of work using rDNA/sDNA
  - Studying genes and genomes
  - Viral or bacterial vectors
  - Constructing modified cell lines
  - Genetically modified plants, animals, and insects
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## What are Biosafety Levels

| 4 RISK CLASSIFICATIONS OF INFECTIOUS MATERIAL |            |           |                                                                               |
|-----------------------------------------------|------------|-----------|-------------------------------------------------------------------------------|
| Risk Group                                    | Individual | Community | Examples                                                                      |
| 1<br>(lowest)                                 | Low        | Low       | non-infectious bacteria<br>-E. coli<br>-lactobacillus spp.                    |
| 2                                             | Moderate   | Low       | -influenza virus<br>-herpes simplex<br>-hepatitis (A, B, C, D, E)<br>-tetanus |
| 3                                             | High       | Low       | -Hepatitis (some C's)<br>-West Nile<br>-Anthrax<br>-TB                        |
| 4<br>(highest)                                | High       | High      | -Ebola virus<br>-herpes B                                                     |



## DRAFT

BSL1

BSL2

BSL3 (WITH RISK-BASED ENHANCEMENTS)

BSL -1 Risk Level

Worker: Low  
Community: Low

BSL -2 Risk Level

Worker: Moderate  
Community: Low

BSL -3 Risk Level

Worker: High  
Community: Low

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### What the Regulation does not do

- Determine locations, buildings, or sites in Watertown where laboratory work is permitted (zoning)
- Regulate life science labs that do not work with rDNA and/or BSL-2 pathogens

#### Take-Away:

If zoning allows laboratory work the WBSC does a technical review to determine if an **individual company** is undertaking work allowed for in the regulation and is utilizing industry best practices

The WBSC does not have oversight over all "Life Science Companies" in Watertown and does not have input into future "Life Science" Developments in Watertown



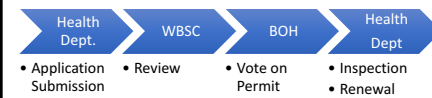
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### Permitting Process



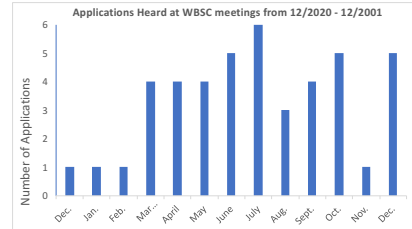
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### Looking to the Future

- Coordination with the Developmental and Planning department to understand the impact of future developments on the WBSC workload
- Coordinate Site Visits by the WBSC to inform WBSC policies
- Provide clarity to the City of Watertown on the WBSC scope and authority



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