



TOWN OF WATERTOWN

Health Department

Larry Ramdin
Director of Public Health

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Application for Recombinant DNA (rDNA) and/or Biologic Agents Permit
Please provide six copies of your application and supporting documents

To the Watertown Board of Health:

The undersigned hereby apply for a permit to use Recombinant DNA (rDNA), and/or Biologic Agents, pursuant to the Town of Watertown's Board of Health regulation: *Biotechnology and the use of Recombinant DNA Molecule Technology.*

Biosafety Containment Level (check all that apply): BSL-1 BSL-2 BSL-3

Application Type: New Renewal

Will there be Large-Scale use (≥ 10 liters of culture in a single vessel)? Yes No

Institution / Company Information:

Name of the Institution: _____

Address: _____

Mailing Address (If Different): _____

Phone: _____ Fax: _____

Institutional Official / Responsible Official / Chief Executive Officer (CEO):

Name: _____

Work Address: _____

Phone (Office): _____ Phone (cell): _____

Email: _____

Check if contact person for permit-related communication

Biosafety Officer:

Name: _____

Work Address: _____

Phone (Office): _____ Phone (cell): _____

Email: _____

Check if contact person for permit-related communication

Contact Person (if none selected above):

Name: _____

Work Address: _____

Phone (Office): _____ Phone (cell): _____

Email: _____

For **NEW** applications, please provide the following documentation:

- A completed and signed rDNA and/or Biologic Agents Permit application form.
- A check or money order payable to the Town of Watertown for \$500.
- A brief, 1-page summary of the work to be performed and the methods to be used.
- A list of all organisms, containment levels, and decontamination procedures to be employed.
- A plot plan showing the proposed location of the facility and a floor plan showing the layout of the facility.
- A plan for a screening process to ensure the purity of strains of host organisms used in experiments and a plan to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics.
- A plan for systematic monitoring of waste to assure that surviving organisms will not be released into the environment (all waste disposal will be done in accordance with 105 CMR 480.000, Chapter VIII, State Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste).
- A plan for systematic pest control management in laboratories, contiguous facilities, and foodservice establishments in the same building.
- A plan for systematic security of the premises.
- Proof of Liability Insurance as detailed in Section 6B-7 of the regulation.
- Documentation of an active Institutional Biosafety Committee (IBC) that adheres to the standards put forth in Section 6B-8 of the regulation.
- The name(s) of the Principal Investigator(s) responsible for enforcing IBC policies.
- The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as outlined in Section 6B-9 of the regulation.
- Description of annual safety training and refresher training provided to laboratory staff.
- A plan for orienting representatives of the Watertown Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
- For **Biosafety Level Three (BSL3)**, documentation establishing the retention of a third-party laboratory commissioning agent with the appropriate experience in the evaluation of facilities employing BSL-3 containment. The Board of Health may select another commissioning agent at its discretion if the third-party agent does not appear to possess sufficient experience and expertise in commissioning BSL-3 laboratories. In addition, documentation of a maintenance schedule and annual inspection by the above described third-party agent.

Applications for **RENEWAL**, please also provide the following documentation:

- A report summarizing work performed over the past year.
- Current list of IBC members
- Copies of the previous year's IBC minutes.

Agreement and Signature

1. We, the undersigned, do here by certify and affirm that all the information provided in this application, including all attached documents, is true and accurate to the best of our knowledge and belief.
2. We certify that we shall conduct work specified in this Permit Application in compliance with the most recent version of the *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* and the Town of Watertown's Board of Health regulation entitled *Biotechnology and the use of Recombinant DNA Molecule Technology*.
3. We understand that an amendment to this Permit must be sought in the following instances: move to a new location within the Town of Watertown, physical expansion of lab space within current facilities, creation of additional lab space at another location in the Town of Watertown, increase in the containment level (BSL) for existing lab space, and/or significant change of protocol (ex. work with a new BSL-3 organism, work with a new Select Agent as defined by the Federal Select Agent Program, new large scale activities as defined in Appendix K of the *NIH Guidelines*). Amendments to the permit must be approved before the above-mentioned changes can proceed.
4. We agree and consent to inspection of our facilities, procedures and practices in order to confirm compliance with the *NIH Guidelines*, the above-mentioned regulation and all applicable federal, state and local laws by the Board or Health or its Agents at reasonable times. Inspections may be conducted annually or with greater frequency if deemed necessary by the Board of Health.
5. We understand that The Board of Health may retain a professionally competent person, agency or institution to perform inspections and reviews at the permit holder's expense as set forth in Section 8 of the regulation.

Institutional Official / Responsible Official / CEO (Signature)

Date

Institutional Official / Responsible Official / CEO (Printed)