

City of Newton

Setti Warren, Mayor



HEALTH AND HUMAN SERVICES DEPARTMENT

Dori Zaleznik, MD, Commissioner
1000 Commonwealth Avenue
Newton, MA 02459-1544

Telephone 617.796.1420 Fax 617.552.7063
TDD/TTY 617-796-1089



Public Health
Prevent. Promote. Protect.

FACILITY LICENSE FOR RECOMBINANT DEOXYRIBONEUCLEIC ACID TECHNOLOGY

The undersigned hereby applies for a Recombinant DNA permit from the Newton Health and Human Services Department in accordance with Section 12-22 of the Revised Ordinances of the City of Newton.

1. Applicant Information

a. Institution: Siamab Inc.

Facility Address: 90 Bridge St. Suite 100, Newton MA 02458

Mailing Address: 55 Chapel St. Suite 004, Newton MA 02458*

Phone: _____ Fax: _____

*mailing address will change Oct. 1, 2015 to 90 Bridge St. Suite 100

b. Contact Person: Jenna Stein

Phone: 857-222-5817 Email: jenna@saimab.com

c. Biosafety Officer: Jillian Prendergast

Phone: 781-927-9734 Email: jill@siamab.com

d. List of Institution Officers (Name, Title, Phone):

1. Jeff Behrens, President and CEO, (617) 500 – 3455

2. Julie DeSander, Senior Director, Corporate Development, (800)513 - 1569

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2. Type of Activity (Mark X where appropriate):

A. Research : B. Storage/Distribution Center: C. Other (Attach):

D. Small Scale: BL1: BL2: BL3: E. Large Scale: BL1:

3. General:

A. How many times did the I.B.C. committee meet in the past year? 0, meeting to be held on TBD

B. Number of employees at this facility: 6 -C. Number involved with rDNA: 3

D. Attach a certificate of general liability

E. Attach list of all organisms used for rDNA at facility (include host, vector, and containment level)

Vectors:

hST6GalNAc I pRc-CMV: human ST6GalNAc cloned into the pRc-CMV vector

Cell Lines:

We use establish tumor cell lines from ATCC including MDA-MB-231, SNU-16, OV90, and OVCAR3. Some cell lines are transfected with the ST6GalNAc I pRc-CMV vector

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E. In the past year, have the following been changed (Mark X where appropriate):

- a. Floor plan of laboratory where rDNA research will occur: [X] – New lab being constructed
- b. Monitoring procedures manual: [] c. Emergency procedure manual: [X] new to facility
- d. Orientation Plan = Public safety officials: [] Local public safety officials: []
- e. Employee orientation protocol: [] f. Medical monitoring protocol: [X]
- g. Insect/rodent control procedures: [X] h. List of all radionuclides used: []
- i. List of all organisms and vectors with biological containment level(s): []
- j. List of Sara Title III Tier 1 and 2 chemical used and quantities: []
- k. List of other communities where license to perform rDNA work: []
- l. Institutional biosafety committee membership list with titles: [X]- new committee

Note: If any changes to the aforementioned, please enclose **new copies**

President & CEO

4. Agreement and Signature

I do hereby swear and affirm that all of the facts contained in this application, including all attachments, are to the best of my knowledge and belief, true and accurate.

For institutions which are not tax exempt: Pursuant to Chapter 62C, Section 49A of the Massachusetts General Laws, I certify under penalties of perjury that, to the best of my knowledge and belief, all state tax returns have been filed and all state taxes have been paid as required under law.

Signature:  Title: _____

Please include your license renewal fee of \$250.00, payable to the City of Newton

Attachment B

Information requested by the City of Newton, Newton Ordinances - Health and Human Services, Article III, Recombinant DNA Research

Siamab Therapeutics, Inc., 90 Bridge St, Suite 100, Newton, MA

Sec. 12-23. Institutional biotechnology committee.

An Institutional Biosafety Committee will be formed in accordance with guidelines of the Newton Code. The IBC will meet on a regular basis and inspect the laboratory areas where rDNA research is being performed annually. The IBC shall immediately notify the commissioner of health and human services and the NBC upon discovery of non-compliance by the institution with any section of this ordinance or the NIH guidelines.

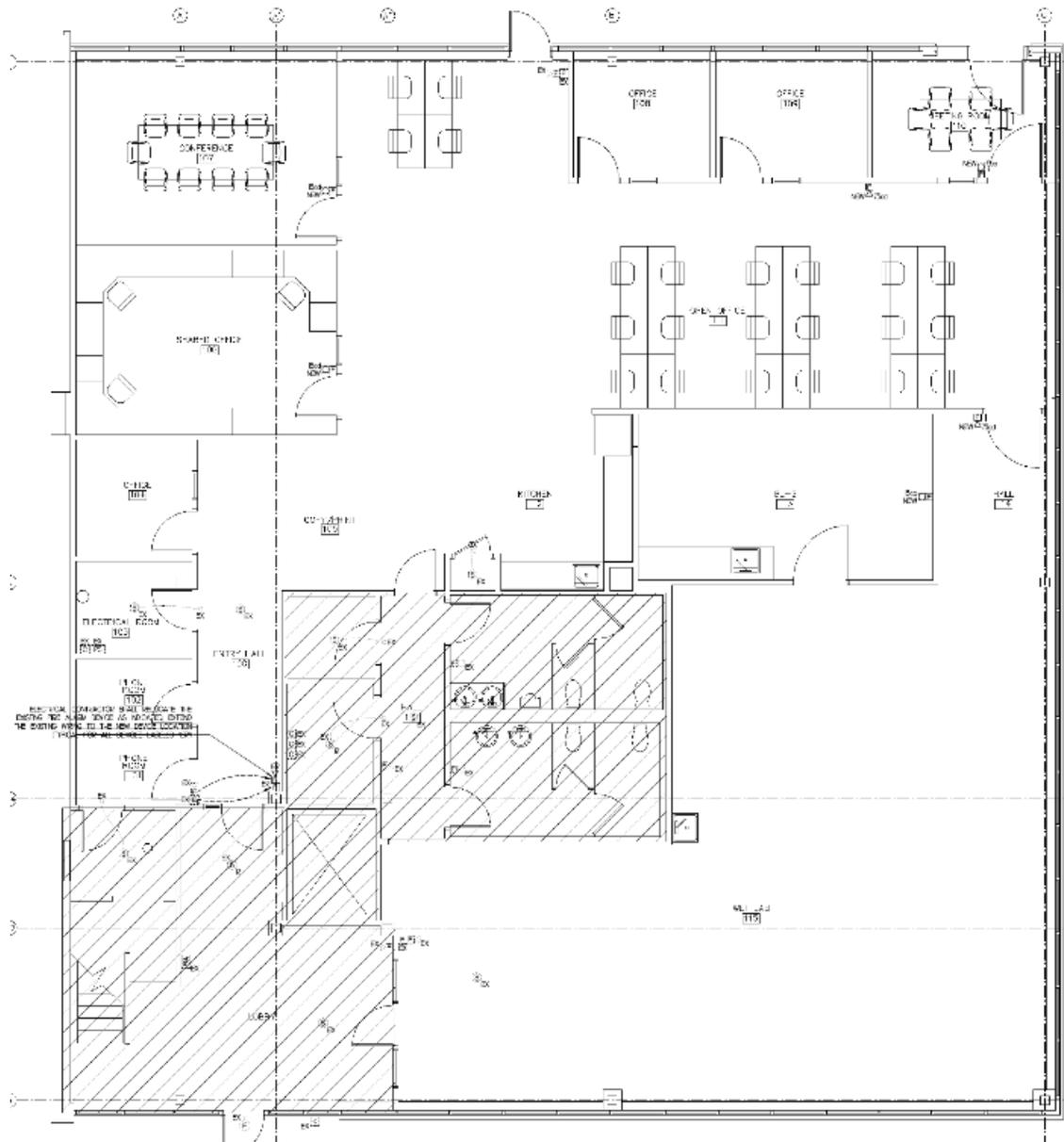
IBC Roster :

- Jillian Prendergast, Biosafety Officer
- Jenna Stein
- David Eavarone
- John Castellot, community member
- Christopher Murphy, community member
- Newton's Commissioner of Health and Human Resources

Section 12-24 (b)(2) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.

See attached maps

90 Bridge St Suite 100 Floor Plan



Siamab Lab Space and Emergency Exits



Siamab Lab Layout



— Lab outline in red

Section 12-24 (b)(3) A listing of all organisms, including containment levels, to be employed in rDNA research or technology, and including the screening process to be performed by institutions conducting rDNA research or technology in order to insure the purity of the strain of host organisms used in the experiments and to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics.

Vectors: hST6GalNAc I pRc-CMV: human ST6GalNAc cloned into the pRc-CMV vector

Cell Lines: Establish tumor cell lines from ATCC including MDA-MB-231, SNU-16, OV90, and OVCAR3. Some cell lines are transfected with the ST6GalNAc I pRc-CMV vector

All work with human materials including cell lines will be performed under BL-2 containment level as specified in the company's Biosafety Manual and Exposure Control Plan.

Section 12-24 (b)(4) A plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.

All wastes will be disposed of in accordance with 105 CMR 480.000, Chapter VIII, State Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste, and all in-house methods of waste treatment will be approved by the IBC. Stericycle will be contracted with for removal of red bag biohazardous waste and sharps.

Section 12-24 (b)(5) Establish a training program of safeguards and procedures for personnel using rDNA.

Siamab will provide safety training as described below for employees:

Emergency Procedures – all employees

- Evacuation Plan
- Basic Fire Extinguisher Safety
- Spill response (chemical, biological)
- Medical emergencies, including locations of Occupational Health and local ER
- Incident reporting

Hazard Communication - all employees

- What is the HazCom Standard
- Labels and signs for chemicals

- Safety Data Sheets (SDS) review
- Chemical Inventory

Chemical Hygiene – all laboratory employees

- Engineering controls
- Administrative controls
- Personal Protective Equipment (PPE)
- Proper handling of chemicals
- Waste handling procedures
- Proper storage of chemicals
- Sink limitations

Biosafety – all laboratory employees

- Identification of Risk Groups
- Working BL2 containment
- Waste procedures (solid, liquid and sharps)
- OSHA Bloodborne Pathogens training

Hazardous Materials Shipping (DOT/IATA)

- DOT for all signers of manifests and for domestic hazmat shippers
- DOT/IATA for all international shippers

RCRA – for all employees handling and managing hazardous waste

Training Records

- Training files will be maintained by Siamab in the central safety file cabinet. Training files include the training date, personnel in attendance, trainer and the training content

Section 12-24 (b)(6) The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC for all persons engaged in the use of rDNA. Effective rodent and insect control programs must be in place.

Siamab's Biosafety Manual and Exposure Control Plan is included with this application. Siamab will be contracted with Mt Auburn Occupational Health to implement a medical surveillance program.

Section 12-24 (b)(7) The name of the safety officer who shall be responsible for enforcing the policies of the IBC.

Jillian Prendergast, Biological safety Officer and is responsible for enforcing the policies of the IBC.

Section 12-24 (b)(8) A plan for orienting representatives of the Newton health and human services, fire and police departments to the physical plant and to procedures to be utilized in the event of an emergency.

Siamab has drafted an Emergency Action Plan (copy included with this application). A copy of this plan will also be sent to the Newton Fire Department and Police Department.