Town of Arlington
Department of Health and Human Services
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Biosafety and Recombinant DNA Regulations

SECTION 1: AUTHORITY

On April 11, 2012 the Arlington Board of Health, pursuant to the authority granted under Massachusetts General Laws (M.G.L.), Chapter 111, Section 31, voted to adopt the "**Biosafety and Recombinant DNA Regulations**" to protect the public health of the community.

SECTION 2: APPLICABILITY/ PURPOSE

These regulations shall apply to all research, production, and other associated activities involving rDNA materials or Biological Agents undertaken within the Town of Arlington, Massachusetts. All such activities shall be undertaken only in strict conformity with these regulations and with current National Institutes of Health (NIH) Guidelines (hereinafter referred to as the "Guidelines") as defined below herein § 3. Any institution engaged in research or production involving rDNA materials or Biological Agents shall also comply at all times with any other applicable federal and state regulations covering such work, including regulations promulgated by the Centers for Disease Control (CDC), Occupational Safety Health Administration (OSHA), Environmental Protection Agency (EPA) Massachusetts Department of Environmental Protection (MADEP) and Massachusetts Department of Public Health (MADPH).

These regulations are promulgated to ensure proper safe guards are in place for work with Biological Agents and recombinant DNA (rDNA) within the Town of Arlington. These regulations promote the safe and responsible conduct of science by institutions utilizing Biological Agents and rDNA materials, and promote competency and adequate training of laboratory staff in laboratory safety.

SECTION 3: DEFINITIONS

Biological agent: any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, or anything capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment. [from the CDC Select Agents and Toxins Final Rule. 42 CFR § 73.1 Definitions]

BMBL: Biosafety in Microbiological and Biomedical Laboratories. The key recommendations for working with biological materials in the United States (US) published jointly by the CDC and the NIH.

BSL: Biological safety level. There are four biosafety levels which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facility containment. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity.

Biosafety Level One Laboratory (BSL-1): All facilities that meet or exceed the criteria for Biosafety Level 1 containment, according to descriptions in the BMBL; appropriate for agents that are not known to cause disease in normal, healthy humans.

Biosafety Level Two Laboratory (BSL-2): All facilities that meet or exceed the criteria for Biosafety Level 2 containment, according to descriptions in the BMBL; appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure.

Biosafety Level Three Laboratory (BSL-3): All facilities that meet or exceed the criteria for Biosafety Level 3 containment, according to descriptions in the BMBL; appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections and that are indigenous or exotic in origin

Biosafety Level Four Laboratory (BSL-4): All facilities that meet or exceed the criteria for Biosafety Level 4 containment, according to descriptions in the BMBL; appropriate for exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available

CDC: Centers for Disease Control and Prevention

EPA: Environmental Protection Agency

Guidelines: The most recent version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register, and any further amendments, wherever published, which are adopted by NIH, or any successor agency thereto.

In the event that the NIH shall abolish or discontinue its Guidelines, those Guidelines in effect at the time of such discontinuance shall remain in effect within the Town of Arlington until further written notice from the Board of Health.

Institution: Any single individual, group of individuals, or organization, whether public or private.

Institutional Biosafety Committee: (IBC) a committee established by an institution in accordance with the Guidelines and the terms set forth in these regulations

Large-scale: The use of more than ten liters of rDNA and/or Biological Agent culture. This threshold shall be based on the cumulative volume of culture in all vessels throughout the institution's facility, not just a single vessel or experiment.

MADEP: Massachusetts Department of Environmental Protection

MADPH: Massachusetts Department of Public Health

OSHA: Occupational Safety and Health Administration

Recombinant DNA molecules (rDNA): in the context of the Guidelines, rDNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Select Agent: Biological materials that have been restricted by the Department of Health and Human Services (DHHS) and the Animal and Plant Health Inspectional Services (APHIS) because of a perceived risk of bioterrorism through improper possession or use. Laboratories that wish to conduct research on these materials must follow strict guidelines that include registration of the entity, laboratory, and personnel with DHHS/APHIS prior to obtaining agents and starting research.

Risk Group: NIH classification of microbiological agents based on association with and resulting severity of disease

Risk Group 1: Agents that are not associated with disease in healthy adult humans

Risk Group 2: Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available

Risk Group 3: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available

Rick Group 4; Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

Any other terms, not specifically defined herein, shall have the meaning as defined in the Guidelines. If the Guidelines do not define the term, it shall have the meaning as is commonly used.

SECTION 4: PERMIT REQUIREMENT

Any institution proposing to process or use Biological Agents or rDNA must obtain a permit from the Arlington Board of Health before engaging in any activity, including construction or renovation of facilities.

SECTION 5: TERMS AND CONDITIONS

1) All rDNA materials and Biological Agents classified as Risk Group 4 agents by the Guidelines, or any work with rDNA materials or a Biological Agent that requires BSL-4 containment based on a biological risk assessment shall be prohibited in the Town of Arlington.
2) Institutions applying for a permit must complete and submit the Plan Review Packet for the use of Biological Agents and/or rDNA within the Town of Arlington. The Director of Health and Human Services or his or her designee will review said application and make its recommendation to the Board of Health. A hearing with the Board of Health will be scheduled within sixty (60) days after the application is filed to take action on the application. The period within which final action shall be taken may be extended for a definite period by mutual consent of the Board of Health and applicant.
3) Each institution must designate an individual as the point of contact for the permit process. This person may be the biosafety officer or responsible official or may serve the institution in another capacity.
4) Institutions must comply with this regulation and the Guidelines at all times.
5) Institutions must allow inspections of both facilities and records, as related to these regulations, in response to emergencies and at other times deemed necessary by the Board of Health.
6) All areas in which rDNA or Biological Agents are utilized shall be free of rodent and insect infestation.
7) Institutions must adhere to a Health and Safety Manual, prepared by the institution, which contains all procedures relevant to the use of Biological Agents and rDNA at all levels of containment at use at the institution. The manual shall also contain a plan for waste disposal in compliance with all applicable federal, state, and local laws or regulations.
8) Institutions must establish and implement a training program of safeguards and procedures for both laboratory personnel using Biological Agents and/or rDNA and non-laboratory personnel who may come into contact with these materials.
9) Each institution shall establish an Institutional Biosafety Committee (IBC) which shall meet at least annually. The IBC shall be established in accordance with the Guidelines defined above, except that the required composition of each IBC shall include at least one representative from the Town of Arlington, approved by the Board of Health. The community member of the IBC shall have no financial interest in the institution or any other institution in competition therewith, and such representative shall be bound to the same provisions as to nondisclosure and nonuse of proprietary information as all other members of the IBC, except to the extent necessary to alleviate any public health hazard.
10) In accordance with the Guidelines, the IBC, acting on behalf of an institution, shall review all rDNA and Biological Agent use for compliance with the Guidelines and

approve those projects that conform to the Guidelines. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying that the experiment conforms with the Guidelines shall be filed with the Board of Health.

11) All institutions shall provide an appropriate medical surveillance program as determined by their IBC and consistent with the Guidelines. Each institution shall submit a description of its medical surveillance program and documentation regarding its implementation as part of its annual report.
12) Each institution shall complete an annual report by April 30 of each year. Said reports must include a summary of the work performed over the past year and addressing any ongoing work and in addition the following:
    a. Current list of IBC members
    b. Copies of the previous year's IBC meeting minutes
    c. Summary of research and any changes in the past year
13) All information sent to the Board of Health shall have all proprietary information and trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the IBC or The Board of Health or its designee(s). The Board of Health and its designee(s) shall maintain the confidentiality of all proprietary information and trade secrets released to them by reason of these regulations to the extent permitted by law. As used in these regulations, proprietary information and trade secrets shall be defined as set forth in under the laws of the commonwealth of Massachusetts.
14) Every applicant shall submit evidence of, and maintain at all times while conducting activities regulated hereunder, a policy or policies of insurance against liability arising out of activities regulated hereunder, for general liability insurance, and contractual liability insurance covering any indemnification required hereunder or by separate agreement, each in an amount of at least $1,000,000 for personal injury or death to any one person, and at least $5,000,000 for personal injury or death from any one incident, and at least $1,000,000 for property damage, and in addition, the institution shall have in full force and effect any other particular or special policy of insurance required by law and the Town of Arlington shall be named as an additional insured in all such policies.
15) Each institution engaging in, or intending to engage in, any activities regulated hereunder agrees to indemnify, defend, protect, and hold harmless the Town of Arlington, its selectmen, officers, agents and employees from and against any and all claims, demands, losses, damages, liabilities, fines, charges, penalties, administrative and judicial proceedings and orders, judgments, remedial actions of any kind, all costs and cleanup actions of any kind, and all costs and expenses incurred in connection therewith, including reasonable attorney's fees and costs of defense (collectively, the "losses"), directly or proximately resulting from the institution's negligence with regard to any acts, omissions or conduct in any way related to any activity regulated hereunder, pursuant to its permit, its application therefore, or resulting from the institution's failure to comply with the terms of the permit, the Regulation of the Guidelines.
16) Permits shall be issued and renewed on an annual basis. The fee for issuance and renewal of permits will be set by the Town Manager.

SECTION 6: LARGE SCALE USE

1) Any institution intending to use Biological Agents or rDNA on a large scale requires the expressed written approval of the Arlington Board of Health prior to conducting any such activity.
2) Any currently permitted institution shall request approval to conduct large scale activity from the Board of Health at least thirty (30) days prior to the initiation of any large scale-related activity, which may include, but not be limited to, construction or renovation of facilities. The Board of Health shall act and make a decision on the request within a thirty (30) day period from receipt of the request. Approval request should come in the form of proposed floor plan of the large scale room and IBC application documenting the proposed research and risk assessment by the Biosafety officer/IBC committee. A formal presentation to the Board of Health may be required to review the materials submitted prior to the Board of Health making a final decision to approve the project(s).
3) Institutions which are not currently permitted shall request approval to conduct large scale activity as part of their application for a Biological Agent or rDNA use permit.
4) During the review of the institution's request, the Board of Health may request additional information from the institution pertaining to the proposed large scale activity.

SECTION 7: EMERGENCY RESPONSE

1) The institution shall report immediately, and in no case more than twenty-four (24) hours, to the Board of Health and any other appropriate authorities any significant problems with or violations of the Guidelines or these regulations, any significant Biological Agent or rDNA- related accidents or illnesses, and any accidental release representing a significant hazard to employees or the public. The initial report shall be provided verbally to the Board of Health, with a written report documenting the initial report to follow within 24 hours. The institution shall provide a final written report to the Board of Health within 30 days of the initial report. The final written report shall include, but not be limited to, information detailing causes, outcomes, response measures, corrective actions and subsequent preventive measures related to the incident.
2) The institution shall provide a plot plan showing the location of all facilities, and a floor plan showing the internal layout of all facilities.
3) The institution shall submit a plan for orienting representatives of the Health, Police and Fire Departments to the facilities and the procedures to be utilized in the event of an emergency.

SECTION 8: ENFORCEMENT

Enforcement of this Regulation shall be the duty and responsibility of the Arlington Board of Health or its designee(s).

SECTION 9: PENALTIES

1) A violation of any condition or restriction of a permit or provision of these regulations shall subject the violator to a fine of three hundred ($300) dollars, or by a criminal complaint in a court of competent jurisdiction. Each day on which any violation exists shall be deemed to be a separate and distinct offense.

2) Once a permit has been issued it may be revoked, suspended, or modified, by the Board of Health, or not renewed upon a determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations or the permit requirements, and terms and conditions, including adherence to the Guidelines.

3) Notwithstanding the above, the Board of Health, upon determination that any violation constitutes an immediate or severe threat to the public health and safety, may order the necessary remedial actions up to and including the immediate closure of any premises or laboratory engaging in or contributing to such threat, without prior notice and hearing but with subsequent notice and hearing within reasonable time.

SECTION 10: EXCLUSIONS

The provisions of this Regulation are not intended to apply to clinical, non-research operations of doctors, dentists and veterinarians within the Town of Arlington when governed by other local, state and federal agencies and regulations.

SECTION 11: SEVERABILITY

The provisions of this section are severable; and if any of the provisions of these regulations shall be held unconstitutional or otherwise invalid by any court of competent jurisdiction, the decision of such court shall not affect or impair any of the remaining provisions.

Arlington Board of Health

Michael Fitzpatrick, DMD, Chair
Gregory Leonardos
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