SEATTLE BIOLOGICAL LABORATORY REGULATIONS

PREAMBLE

Biotechnology research promises advances in fields ranging from medicine and agriculture to combating bio-terrorism. It is a well funded and rapidly growing enterprise in research centers around the United States, including Seattle.

As with other technologies such as nuclear energy, research in biotechnology also carries risks. Some materials used in biotechnology labs are dangerous and/or environmentally destructive. Improper handling of those materials could cause loss of life, personal injury, environmental destruction and property damage.

Although research in biotechnology is relatively new, exposures to dangerous substances from various biotechnology labs around the country, including exposures at a biotechnology lab operated in downtown Seattle, already have occurred. Nonetheless, biotechnology research in Seattle is largely unregulated. Indeed, human exposures have occurred without the public ever being informed.

Safe and responsible biotechnology research requires that the research be transparent, subject to independent oversight and regulation, and that violations of those regulations be effectively sanctioned. These regulations are established in order to accomplish those ends.

I. BIOLOGICAL RESEARCH LABORATORY HEALTH AND SAFETY PROGRAM FOR SEATTLE

A. Definitions.

1. "Biological Agent." Any naturally occurring, bioengineered, or genetically altered or synthesized micro-organism (including bacteria, virus, fungus and protozoa), or infectious substance or vector, or component of any such micro-organism or infectious substance capable of causing death, disease, or other physiological change in a human, an animal, a plant or other living organism; deterioration of food, water, equipment, supplies, or material of any kind; or having a deleterious effect on the environment.

2. "Biosafety Level 2 Laboratory" (BSL2). A laboratory that is designed, equipped or operated as a Biosafety Level 2 Laboratory as defined by the United States National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

3. "Biosafety Level 3 Laboratory" (BSL3). A laboratory that is designed, equipped or operated as a Biosafety Level 3 Laboratory as defined by the United States National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

4. "Biosafety Level 4 Laboratory" (BSL4). A laboratory that is designed, equipped or operated as a Biosafety Level 4 Laboratory as defined by the United States National

Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

5. "BOH." King County Board of Health, aka Public Health - Seattle & King County.

6. "Facility." A building or combination of buildings under common control and ownership containing one or more laboratories subject to a common Institutional Biosafety Committee (as defined in Section II, *infra*).

7. "Laboratory." A room or rooms used primarily for biological research, development, non-routine testing, or experimentation activity, or any room or rooms where vertebrate animals are contained under animal biosafety levels described in NIH Guidelines. The word laboratory also includes all enclosed areas with a laboratory containment area, including any rooms, closets, facilities, freezers, refrigerators or incubators where biological agents are stored, fermented, grown, proliferated or colonized.

8. "Research Sponsor." Any State, public or private corporation or authority, any individual, trust, firm, joint stock company, LLC, partnership, research group, task force, university program, association, or entity or any group thereof, any group of persons, and any agency or political subdivision of the State of Washington, the federal government or any other government, subdivision, agent or agency thereof, which operates or which proposes to operate a BSL2 and/or BSL3 laboratory in Seattle.

9. "Principal Investigator." The individual designated by a Research Sponsor to direct the biological research project or program the Research Sponsor conducts at biosafety laboratory levels 2 or 3, who is responsible to the Research Sponsor for the scientific and technical direction of that project or program.

10. "Toxin." Any toxic material or product of plants, animals, micro-organisms (including bacteria, virus, fungus, rickettsia, or protozoa), misfolded protein, infectious substance, or a recombinant or synthesized molecule, whatever its origin or method of production. "Toxin" includes: any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such substance.

B. There shall be established in the BOH, a High Containment Biological Research Laboratory Health and Safety Program ("the Program") for BSL2 &3 laboratories located in Seattle.

1. The Program shall provide standards for location, operation, and maintenance of High Containment Biological Research Laboratories and the oversight of such laboratories to protect the safety of laboratory workers, the public, and the environment from regulated agents and toxins.

2. The Program shall provide standards for the transportation, relocation, shipment, delivery, conveyance and receipt of regulated agents and toxins.

3. The Program shall provide for procedures which would allow the BOH to order a Biosafety Laboratory Levels 2 through 3 to immediately cease and desist work on a project(s) and lock down and/or refrain from any activity that the BOH determines could cause immediate and irreparable injury, loss or damage.

4. The Program shall be administered by the Seattle Biosafety Committee defined below.

C. The BOH shall adopt regulations for the implementation of the Program that establish the criteria for determining appropriate locations for siting a building or facility that contains a laboratory defined by this regulation, including whether a laboratory may be created within an existing building. The criteria will include at a minimum that:

1. Sites shall not be within a flood plain, within 800 yards of property whose regular use could endanger the site due to fire or explosion; or near an area of traffic congestion that might impede emergency access for evacuation or endanger motorists or pedestrians.

2. Sites shall have sufficient land available to provide for a reasonable buffer around the buildings which shall be no less than 150 unobstructed feet in each direction.

3. Other criteria for consideration shall include proximity of wetlands, waterways and water bodies; the relationship of the site to groundwater elevation; the nature and extent of residential areas and schools in proximity to the site; the availability and suitability of access roads to the site, including the ability of first responders to access the site in an emergency; the potential for adverse public health and safety impacts; potential impact of increased traffic volume on adjacent roads; and the potential threat of terrorist attack or infiltration of the building.

4. The BOH shall set forth procedures, consistent with this regulation, for the submission, review and approval of permit and construction applications, and the issuance and renewal of permit and construction applications. Permits may be issued which contain conditions or restrictions that serve and protect public health and safety.

a) Application for a permit or renewal of a permit shall be acted upon within 60 days of submission of a completed application. The BOH is not obligated to review incomplete applications. If, at the conclusion of the 60 day period, the review of the application is not complete, the BOH may issue to a Research Sponsor a provisional permit if the application is complete and it establishes substantial compliance with these regulations. A provisional permit shall not exceed 120 days in duration, and shall not be renewed or extended.
b) To the extent that the permit application may require the submission or review of trade secret information as defined by RCW 19.108.101, the Research Sponsor may submit such information under seal. Committee members and their staff shall be prohibited from

disclosing trade secret information submitted under seal pursuant to this provision to any third party, and such matter shall be used by the commission and its staff for no purpose other than the permitting process. Reckless or intentional disclosure of trade secret information submitted under seal shall be a misdemeanor punishable by up to 1 year in jail.

c) The denial of a permit application may be appealed pursuant to the Rules of Practice and Procedure of the King County Board of Appeals.

d) Prior to issuance of any permit for a BSL 3 laboratory under these regulations, the BOH must hold, with 60 days notice to the public of the application and its contents, a public hearing on the application with opportunity for reasonable public comment on whether the application should be granted.

II. SEATTLE BIOSAFETY COMMITTEE

A. The BOH shall appoint a Seattle Biosafety Committee (SBC) composed of both scientific and community representatives drawn from lists submitted to it from community and neighborhood organizations, universities, colleges, and public interest organizations located within the City of Seattle to assist in regulating biological laboratories and facilities operating under the auspices of these regulations. The SBC shall include at least nine members and one salaried Executive Director who shall be selected by the BOH for a term of four years. Members will be appointed for a two-year term and may be removed only for cause. Members shall have no financial, professional, familial, close social or business relationship in or with the regulated Research Sponsors, their affiliates, subsidiaries, employees, contractors, sub-contractors, investors or funders. Members appointed to fill vacancies shall serve for a full term. Any member of the SBC is eligible for reappointment for up to three consecutive terms. Members of the SBC shall serve without compensation but their reasonable costs and expenses shall be reimbursed by the BOH.

B. The SBC shall periodically report to the BOH and provide technical assistance, review of the effectiveness of these regulations and advise and/or deliberate as needed about technical issues arising out of permits and applications of these regulations.

C. The SBC shall consider policy changes or possible amendments to the regulations, improve the system of laboratory and facility regulation, for the safe handling, relocation, shipment, delivery, conveyance, receipt and transportation of biological agents or toxins and deliberate as needed.

D. The SBC shall meet monthly or with sufficient frequency to assure its ability to carry out its duties and responsibilities.

III. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC).

A. A Research Sponsor that holds a permit issued pursuant to these regulations shall have an Institutional Biosafety Committee (IBC) for each facility to ensure the public safety and conformance with these regulations. Composition of the IBC shall include at least two community representatives who have no financial, professional, familial, close social or business relationship in or with the regulated Research Sponsor, its affiliates or subsidiaries, employees, contractors, sub-contractors or investors . Community representatives shall be selected by joint approval of the BOH and neighborhood organizations representing the communities or community where the laboratory is located. Community representatives shall be individuals whose principal residence is within 3 miles of the laboratory, and whose principal residence has been within 3 miles of the laboratory for at least the 2 years immediately preceding their selection as such.

B. Each IBC shall report to the SBC. The IBC will meet at least four times a year and at such other times as may be specified by the SBC, or guidelines issued under these regulations, or as requested by any member of the IBC. Except for executive sessions, meetings of the IBC and all of its sub-committees shall be open to the public. Notice of such public meetings and the conduct of public meetings shall be in accordance with the Washington State Public Meetings Act.

C. Each IBC shall file an annual report with the SBC. The report shall include, at a minimum, complete copies of all IBC minutes for the preceding reporting period, certification that the laboratory and/or facility is in compliance with these regulations, a report on any quality assurance and quality improvement efforts made during the period, a complete roster of current IBC members, and an update of any information relative to the permit application. To the extent IBC minutes contain information that jeopardizes trade secret information as defined by RCW 19.108.101, the SBC shall develop procedures for assuring confidentiality of said information. IBC minutes shall, at a minimum, conform to NIH Office of Biotechnology Activities (OBA) issued guidance concerning the preparation of, and public access to, minutes of Institutional Biosafety Committee meetings (available at http://www4.od.nih.gov/oba/IBC/IBC_Minute_Q_A.pdf) and Department of Health & Human Services Guidance on the Content of Minutes of Institutional Biosafety Committee Meetings, dated February 23, 2007 (available at http://www4.od.nih.gov/oba/IBC/IBC_Minutes_Guidance_Feb_23_2007.pdf)

IV. PERMIT FEES

The BOH is hereby authorized to establish fees for the issuance and renewal of permits which may vary according to the type of use and scale of activity being conducted. All fees shall be directly related to the costs incurred by the BOH and/or the SBC for any issuance of permits, the inspection of laboratories, and any other costs associated with implementation of these regulations. Full payment of such fees shall be a condition for the granting or renewal of any permit.

V. BOH PREAPPROVAL REQUIRED FOR CERTAIN RESEARCH

A. Any Research Sponsor operating or proposing to operate a biological laboratory or laboratories, or any Research Sponsor conducting or proposing to conduct any biological research at BSL Levels 2 or 3, shall obtain a permit from the SBC. The permittee shall insure that all persons in such laboratories comply with the requirements set forth herein and the regulations issued thereunder.

B. Each permit application shall include the following:

1. Name and location of the Research Sponsor;

2. The location and biosafety level rating or ratings for each laboratory that will operate under the permit;

3. Roster, biographical information and contact information of the Institutional Biosafety Committee indicating the Chair, and community members;

4. Name, title and contact information of each of the following: 1) a health officer responsible for the health of the laboratory or facility, known as the "health officer", 2) an officer responsible for biological safety at the laboratory or facility, known as the "biological safety officer" and 3) an official responsible for the overall operation of the laboratory or facility, known as the "responsible official";

5. Project information including, but not limited to, title and brief description of the project, grant identification number or other unique institutional identifier number, the principal investigator and the agent or agents used in the project including all biological agents and toxins for each project or program;

6. Procedures and policies relating to laboratory safety including, but not limited to, research, training, security, laboratory inspections, transportation, waste disposal, commissioning, decommissioning, decontamination, termination of work with biological agents and toxins, training of all employees, visitors or students and first responder plans including evacuation and emergency response;

7. Such other information as required by the SBC and guidelines issues hereunder; and

8. Any incident in which the Research Sponsor, any of its officers, employees or any other person who will work in the lab or exercise authority over activity in the lab was found to have violated, or was sanctioned for violating, any law, regulation or ordinance regulating the environment, health, safety, public disclosure and/or the truthfulness of statements.

VI. EMERGENCY SUSPENSION OF PERMIT

Should the Director of BOH become aware of credible evidence that activity at a facility licensed for, or seeking a license for operation under these regulations is likely to pose a significant and imminent threat to human health or to the environment or to cause substantial property damage, the Director may find that immediate closure of the facility is required to avert such danger and order all research and related activity at that facility suspended until such time as the Director finds that threat to have been resolved. If the Research Sponsor believes the Director's finding to have been unwarranted, it may seek reversal of the decision in the King County Superior Court based on clear and convincing evidence.

VII. REPORTING REQUIREMENTS

A. The licensed Research Sponsor must, within 24 hours, report to the SBC any incident in which there was human exposure to a biological agent or toxin, and/or a reasonable likelihood of such exposure, including all incidents resulting in actual or recommended prophylactic quarantine or drug use.

B. A Research Sponsor shall report any release or spread of a biological agent or toxin, or the reasonable likelihood of a release or spread, outside the primary containment area of a BSL laboratory to the BOH as soon as possible and in no case more than 24 hours after the event. The report shall also be provided to the Seattle Biosafety Committee.

C. The facility or laboratory shall also provide the IBC with a detailed report of all incidents, accidents and other events that cause or are suspected to have caused a threat to the public health, death, illness, or bodily injury to any person to report said incident not later than 72 hours after the incident. The report shall be a public record.

D. On an annual basis, the facility or laboratory shall provide SBC with Third Party Certification for all biosafety cabinets, autoclaves, tissue digesters, incubators, centrifuges, and all other major laboratory equipment.

VIII. TRAINING

Each facility with a laboratory defined under these regulations shall have and implement a plan to provide adequate training for the proper handling of biological agents and toxins that might be present therein. Such training shall include, but not be limited to, decontamination methods, personnel safety precautions and work habits, early warning disease surveillance, and accident response actions and notifications, access control and monitoring, personnel management, inventory and accountability, information security and transport of biological agents Each facility shall provide a training plan to its IBC and to the SBC for approval and shall update the plan annually, or as necessary. The training plan shall ensure that all laboratory staff, facility workers and researchers, including the Principal Investigator for each facility, are trained adequately. The Principal Investigator shall participate in the creation and implementation of the training plan. No individual other than a local, State or Federal government representative

with authorized access for regulatory compliance for investigative purposes may enter the BSL laboratory located within a facility without first completing the facility's training plan.

IX. WASTE MANAGEMENT

Each facility regulated by these regulations shall implement a waste management and decontamination plan submitted to and approved in advance as a condition of permitting by the SBC.

X. EMERGENCY RESPONSE PLAN

A facility regulated by these regulations shall develop an emergency response plan, in conjunction with local and State officials, that addresses security threats and releases involving the spread of biological agents and toxins. The emergency response plan shall comply with local, State and federal plans already in existence. The plan must address such events as severe weather, earthquakes, power outages, power line breaks, terrorism, and other natural, accidental or intentional disasters or emergencies. The emergency response plan shall, at a minimum, address the following:

1. Particular hazards associated with specific biological agents and toxins located at the facility or its laboratories;

2. Personnel roles, lines of authority, training, and communication;

3. Emergency assessment and prevention;

4. Site security and control;

5. Evacuation routes and procedures;

6. Decontamination;

7. Emergency medical treatment and first-aid;

8. Emergency alerting and response procedures;

9. Personal protective and emergency equipment;

10. Regulatory scheduled preparedness exercises coordinated with Seattle Public Health and Safety Officials;

11. Critique of response and follow-up subsequent to an incident; and

12. Communication to the public and the local news media.

XI. INSPECTIONS

The SBC shall have the authority to review all documentation relating to the operations of the facility and any laboratories therein, and to conduct a physical inspection of any facility or laboratory, with or without prior notice, so long as such inspection is conducted at a reasonable time under the circumstances and in a manner that maintains the health and safety systems of the laboratories involved. Failure to provide any requested documentation or access to a laboratory for the purpose of inspection will result in a fine and/or the immediate suspension or restriction of a Research Sponsor's permit to operate. A failure to provide requested documentation or access to a laboratory for the purpose of inspection for a period exceeding 7 days shall result in suspension of the facility or laboratory permit to operate at least until such time as the failure has been rectified.

XII. PROHIBITIONS

A. Any BSL Level 2 or 3 research or project is forbidden in the City of Seattle if it is reasonably likely to:

1. To be used to harm human health, human habitat, agriculture, or the breeding or raising of livestock;
2. Render an immunization ineffective or lessen immunity in humans, animals or plants;
3. Confer to a biological agent or toxin resistance of clinically and/or agriculturally useful prophylaxes or therapeutics against that agent or toxin;
4. Enhance the virulence of a biological agent or render a nonpathogen virulent;
5. Enhance the ease of transmission of a biological agent from human to human, animal to animal or animal to human;
6. Enable the evasion of diagnostic/detection modalities;
7. Alter the host range or vector of a biological agent or toxin;
8. Enhance the susceptibility of a host population; or
9. Create a novel biological agent or toxin, reconstitute or revitalize an eradicated, inactive, dormant or extinct biological agent that is harmful to humans, human habitat, agriculture or livestock.

B. A Principal Investigator may seek an exemption to the prohibitions listed in Section XII(a) for a specific research project by submitting to the SBC, in advance, a written request which specifies in detail the precise research proposed to be carried out, the purpose and need for the exemption, the names of all Research Sponsors for the research that will be subject to the exemption, the unavailability of alternative means of conducting the research, a clear explanation of any special risks involved in the research or project proposed for exemption, and any extraordinary safeguards and precautions which need to be implemented. The SBC may permit exemptions to the prohibitions listed in Section XII(A), above, only on a research project by project basis; it may not issue a blanket exemption to any particular Principle Investigator or

Research Sponsor, nor may the SBC issue a blanket exemption for a particular type of research project. Any exemption permitted under this section shall be updated and resubmitted to the SBC annually for review and reconsideration. Research or projects that are subject to the prohibitions described in Section XII(A) shall not be exempted solely on the basis that the research or project has dual purposes or uses, some of which may not violate Section XII(A).

C. BSL4 laboratories and facilities that contain them shall not be permitted within the City of Seattle.

XIII. NOTICE POSTING AND DISTRIBUTION OF REGULATIONS

A. A copy of these regulations shall be distributed to all employees, students and any other person who has regular access to any portion of a facility or laboratory permitted hereunder. All entities permitted pursuant to these regulations shall have a system for reporting health and safety violations, including a method to report in an anonymous manner to the Health and Safety Officer and a method to report in an anonymous manner to the IBC.

B. No person shall be required to conduct scientific research, experimentation, study or take other action in a laboratory that violates any provision of these regulation or permits issued hereunder or has reasonable potential to adversely affect public or employee health and safety. No person or employer shall discharge, refuse to hire, discipline or in any manner retaliate or take any adverse action against any employee, applicant or other person because such employee, applicant or person discloses or threatens to disclose to a supervisor or a governmental agency an activity, policy or practice that the person reasonably believes is in violation of these regulations; or objects to or refuses to participate in any activity, policy or practice that the person reasonably believes is in violation of this regulation. In addition to any other remedy provided by law, an employee, researcher or student aggrieved by a violation of this subsection, within two years, may file a complaint with the Seattle City Attorney, who, after a proper investigation, may, in proper circumstances, bring an action in the name of the City against the facility alleged to have violated this section. If the Seattle City Attorney declines to bring an action based on the complaint filed, it shall expeditiously provide notice of decline to the grievant. The aggrieved employee, researcher or student may, within one year after said notice, institute a civil action in the Superior Court of King County. Any party to said action shall be entitled to trial by jury. Remedies available in common law tort actions shall be available to prevailing parties, in addition to any legal or equitable relief. The court may, in addition to issuing temporary restraining orders, preliminary or permanent injunctions, order the reinstatement of an employee's, researcher's or student's position, the restatement of salary and fringe benefits and rights, compensation three times lost wages and benefits or other remuneration, interest for liquidated damages and/or repayment by the facility of employee's, researcher's or student's reasonable costs and attorneys' fees.

XIV. VIOLATION OF REGULATIONS

A. The intentional or reckless violation of any conditional restriction of a permit or any provision of these regulations shall subject the violator to conviction of a gross misdemeanor with a maximum fine of up to $5,000.00. Each such violation shall constitute a separate and distinct offense. Any false statement contained in an application for a permit under these

regulations or in any report or disclosure required under these regulations, including a false statement that matter is a 'trade secret,' will constitute a 'violation' subject to the sanctions listed in section XIV of these regulations.

B. Any violation of any of these regulations at the lab or pertaining to the lab or any violation of any condition or restriction on a lab permit, regardless of the identity or affiliation of the violator, may result in the suspension of the Research Sponsor's permit to operate one or more laboratories for a period of not less than one year, and may result in more serious sanctions including permanent revocation of the permit and assessment of a civil penalty against the Research Sponsor of up to $300,000.00. Where such violation was caused by the reckless or intentional conduct of Research Sponsor or agent thereof, suspension of the Research Sponsor's permit to operate the laboratory at which the violation occurred for a period of not less than one year and assessment of $300,000.00 civil penalty against the Research Sponsor shall be the minimum sanction. Each such violation shall constitute a separate and distinct ground for sanction under this section.

C. Any violation of any of these regulations at the lab or pertaining to the lab or any violation of a condition or restriction on a lab permit, regardless of the identity or affiliation of the violator, which is preceded by two prior such violations will result in revocation of all the Research Sponsor's permits to operate any BSL2 or BSL3 laboratory for a period of 2 years, and in the preclusion of the Research Sponsor's obtaining any additional permits to operate any BSL2 or BSL3 laboratory for a period of 2 years.

XV. EFFECTIVE DATE

These regulations shall take effect within ninety (90) days from the date of passage.

XVI. SEVERABILITY

Any section, subsection, sentence, clause or portion of these regulations that is for any reason held invalid or unconstitutional by any court of competent jurisdiction, shall be deemed a separate, distinct and independent provision, and such holding shall not affect the validity of the remaining portions of these regulations.