1.0 Introduction
Cornell University is committed to integrity and excellence in teaching, research, and diagnostic activities. To support these activities responsibly, the University will implement policies and procedures that are designed to maintain a safe environment for all members of the campus and Ithaca community. This program document defines the operational framework at Cornell University for research and diagnostic activities conducted at Biosafety Level 3 (BSL-3) and animal Biosafety Level 3 (ABSL-3).

BSL-3 practices, safety equipment, and facility design and construction are applicable when work is conducted with the following: indigenous or exotic agents with a potential for respiratory transmission, as well as mucous membrane exposures and ingestion, and which may cause serious and potentially lethal infection. BSL-3 facilities and practices are also required for working with
animal or plant biohazardous materials (including Select Agents) that do not pose a risk to human health, but require strict biocontainment to prevent their release into the environment.

Cornell BSL-3 requirements will align with those practices described in the Centers for Disease Control and Prevention and National Institutes of Health (CDC/NIH) “Biosafety in Biomedical and Microbiological Laboratories” (BMBL), 5th edition (http://www.cdc.gov/biosafety/publications/bmbl5/index.htm) and other applicable guidelines regarding the design of facilities, and the recommended practices and safety equipment.

The Institutional Biosafety Committee (IBC) is responsible for the review and approval of activities conducted at BSL-3. The review will include a comprehensive analysis of the risks. The risk analysis will evaluate the appropriateness of the biosafety level, the microbiological practices, procedures and safety equipment to be used, facility safeguards, and administrative and management measures that will be implemented. The Institutional Biosafety Committee (IBC), Office of Research Integrity and Assurance (ORIA), Environmental Health and Safety (EHS), College of Veterinary Medicine (CVM), and Gannett Health Services (GHS) work together to assess that activities performed at BSL-3 comply with external regulations and applicable University policies and procedures.

2.0 Objective

This document describes the structure of the BSL-3 program at Cornell University and establishes requirements and guidelines for the review and approval of: protocols that use infectious or biohazardous material classified at risk group level 3 by CDC, NIH and BMBL; laboratory or animal BSL-3 facilities, operational oversight of these facilities; personnel training and testing; occupational health and medical surveillance; and exposure reporting. Key requirements of the BSL-3 program at Cornell consist of the following:

2.1 An Approved Memorandum of Understanding (MUA) and BSL-3 Application and IACUC Protocol if applicable;
2.2 A risk assessment of agent and activities;
2.3 Laboratory specific manual that includes approved research/diagnostic and facility specific standard operating procedures (SOPs);
2.4 Training and demonstration of proficiency;
2.5 Enrollment in Medical Screening and Surveillance;
2.6 Enrollment in Respiratory Protection Program (RPP), if applicable.
3.0 Applicability
The program requirements are applicable to all personnel engaged in research, diagnostic activities, animal husbandry, and facility maintenance (including safety personnel) within laboratory or animal BSL-3 facilities on the Ithaca, NY campus.

4.0 Definitions
4.1 AAALAC Association for Assessment and Accreditation of Laboratory Animal Care International. A private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. See www.aaalac.org/.

4.2 BSL-3 Advisory Committee (BAC) The Biosafety Officer (BSO) will assemble a BAC to assist in the evaluation of the BSL-3 application. The BAC will function as a subcommittee to the Institutional Biosafety Committee and will be comprised of at least the following: BSO, Biosafety Engineer (BE), Biosafety Level 3 Specialist (BSS), a representative from the Occupational Medicine Program at Gannett Health Services, two principal investigators from the IBC, as well as a CARE veterinarian, animal facility manager, and IACUC member, when applicable.

4.3 Biohazardous Materials Infectious/pathogenic agents classified as Risk Group 2 or higher bacterial, fungal, parasitic, viral rickettsia or chlamydial agents, as well as cell cultures, tissues, human-derived materials, biological toxins, and recombinant DNA molecules that have the potential for causing disease in healthy humans or animals.

4.4 BSL-3 Biosafety Level 3. BSL-3 practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission as well as mucous membrane exposures and ingestion, and which may cause serious and potentially lethal infection. Primary hazards to personnel working with these agents relate to autoinoculation, ingestion, direct contact, mucous membrane exposure, and exposure to infectious aerosols.

See http://www.cdc.gov/od/ohs/biosafety/bml5/sections/SecurityIV-Inbed link LaboratoryBiosafetyLevelCriteria.pdf. BSL-3 facilities and practices are also required for working with animal or plant biohazardous materials (including infectious and Select Agents). While these do not pose significant risk to human health, they require strict biocontainment to prevent their release into the environment.

See http://www.cdc.gov/biosafety/publications/bml5/index.htm Appendix D.

4.5 CARE Cornell Center for Animal Resources and Education. CARE is responsible for the administration of the Animal Care and Use program in compliance with state and federal regulations and university policy. See www.research.cornell.edu/care.

4.6 CDC Centers for Disease Control and Prevention. See www.cdc.gov.
4.7 **Containment** Describes safe methods, facilities, and equipment for managing infectious materials in an environment where they are being handled or maintained. The Purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the release of infectious materials to the outside environment.

4.8 **Exposure** Contact with infectious agents in a manner that can result in transmission and the possible development of disease.

4.9 **Gannett Health Services** Gannett is the primary health care provider for the Cornell community. The Occupational Medicine team at Gannett is staffed by medical and nursing professionals with specialty certifications in occupational medicine, internal medicine, public health, hearing conservation, and spirometry. See [http://www.gannett.cornell.edu/services/occupational/index.cfm](http://www.gannett.cornell.edu/services/occupational/index.cfm).

4.10 **HASP** Hazard Assessment Signage Program

4.11 **HEPA** High Efficiency Particulate Air

4.12 **IACUC** Institutional Animal Care and Use Committee. The IACUC is responsible for oversight of the Animal Care and Use program and monitoring its compliance with applicable federal and state regulations and appropriate guidelines. See [www.iacuc.cornell.edu](http://www.iacuc.cornell.edu).

4.13 **IACUC Protocol** The primary application form of the IACUC, to be completed by and investigator and describes research, teaching, and service activities that involve the use of live vertebrate animals. See [https://esirius.research.cornell.edu/esirius/](https://esirius.research.cornell.edu/esirius/).

4.14 **IBC** Institutional Biosafety Committee. The IBC is responsible for oversight of the use of biohazardous and infectious materials and of recombinant DNA. It is the local oversight body for compliance with the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). See [www.ibc.cornell.edu](http://www.ibc.cornell.edu).

4.15 **Principal Investigator** The Principal Investigator (or PI) is an individual who has responsibility for the design and implementation of research that uses biohazardous or infectious materials.

4.16 **Medical Screening and Surveillance** Medical screening and surveillance are the ongoing systematic collection, analysis, and interpretation of health data for purposes of promoting health and safety.

4.17 **MUA** Memorandum of Understanding and Agreement. The MUA, the primary application form of the IBC, is completed by an investigator and describes research, teaching, and service activities that involve the use of regulated recombinant DNA and biohazardous materials. See [https://ibc.research.cornell.edu/ibc/index.cfm](https://ibc.research.cornell.edu/ibc/index.cfm).

4.18 **NIH OBA** National Institutes of Health, Office of Biotechnology Activities promotes science, safety, and ethics in biotechnology through advancement of knowledge, enhancement of public understanding, and development of sound public policies such as the recombinant DNA Guidelines ([http://www4.od.nih.gov/oba/](http://www4.od.nih.gov/oba/)).

4.19 **Occupational Medicine** Occupational medicine is the branch of medicine that deals with prevention, diagnosis, and treatment of work-related injuries and illnesses.
4.20 **ORIA** Office of Research Integrity and Assurance. ORIA has responsibility for managing, supporting, monitoring, and assessing Cornell’s research compliance programs. See [http://www.oria.cornell.edu](http://www.oria.cornell.edu).

4.21 **PAPR** Powered Air Purifying Respirator.

4.22 **Piggybacking/Tailgating** An unauthorized means of gaining entry into a facility by following an authorized individual through the main entrance of a BSL-3 space.

4.23 **Recombinant DNA** 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 molecules that result from the replication of those previously described.

4.24 **Select Agents** Biological agents and toxins that have the potential to pose a severe threat to the public, animal or plant health, or to animal or plant products. Possession and use of these agents requires registration with the BSO. These agents are regulated by the CDC and USDA.


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5.0 **BSL-3 Personnel**

This section describes the roles and responsibilities of the stakeholders who directly conduct BSL-3 work or support the University BSL-3 program.

5.1 **Animal Facility Manager:** Is responsible for coordination and oversight of operational, maintenance, and repair activities in facilities and spaces that use animals, and supervises activities of support personnel.

5.1.1 Coordinates the receipt, shipment and transport of animals within the facility;

5.1.2 Assists with investigation and remediation of physical and operational failures (e.g., HVAC alarms);

5.1.3 Coordinates the certification and maintenance of animal containment equipment within the facility and maintains SOPs for doing so;

5.1.4 Assist with development and implementation of safety, security and emergency response procedures, and participates in emergency response activities;

5.1.5 Support BSL-3 Program Team with response to nonconformance issues (e.g., by changing access rights as requested);

5.1.6 Serves as the primary interface with the CVM facilities Office for implementation of the CVM’s pest (insect/rodent) control programs within the facility;

5.1.7 Assists the BSL-3 Program Team with periodic testing of BSL-3 autoclaves;

5.1.8 Coordinates animal husbandry activities within a facility;

5.1.9 Leads development of animal husbandry SOPs;
5.1.10 Assigns space within suites of labs/animal rooms for investigator use;
5.1.11 Provides animal census, space, and PPE use data to appropriate accounting personnel for collection of user fees;
5.1.12 Acquires support equipment (telephones, cabinets, carts, mirrors, shelves, etc.);
5.1.13 Programs personnel approved by the BSL-3 Program Team into the facility’s access control system;
5.1.14 Provides training to CARE staff (e.g., module 2 for animals);
5.1.15 Leads the PPE ordering and stocking efforts for animal facilities;
5.1.16 Participates in the GHS medical screening and surveillance requirements;
5.1.17 If applicable, is medically cleared and fit tested to wear the appropriate respirator.

5.2 Biosafety Engineer (BE): Serves as the lead technical resource for the BSL-3 facilities at the College of Veterinary Medicine.
5.2.1 The BE is a member of the BSL-3 Program Team;
5.2.2 Leads the facility commissioning process, provides review for the final report and documents acceptance;
5.2.3 Leads the annual verification, decontamination/fumigation, and annual maintenance activities;
5.2.4 Leads the validation of fumigation processes and autoclaves;
5.2.5 Leads the maintenance of BSL-3 infrastructure (i.e., HVAC, waste disposal, and related building systems) with users and facilities operations/maintenance staff.
5.2.6 Investigates and assists with remediation of physical and operational failures (e.g., HVAC alarms);
5.2.7 Leads development and review of facility-related (e.g., HVAC alarms) standard operating procedures (SOPs);
5.2.8 Leads the periodic download of card reader access histories;
5.2.9 Participates in the development and delivery of BSL-3 related training;
5.2.10 Acts as an informational resource for biosafety practices and procedures;
5.2.11 Assists with emergency response activities;
5.2.12 Assists with approval of personnel for access to BSL-3 space;
5.2.13 Assists with escorting of approved visitors;
5.2.14 Serves as a member on the IBC and BAC;
5.2.15 Participates in GHS medical screening and surveillance requirements;
5.2.16 Is medically cleared and fit tested to wear the appropriate respirator.

5.3 Biosafety Officer (BSO): Establishes and monitors health and safety procedures that are designed to minimize or prevent injury or potential exposure to biohazardous materials, in accordance with University policies.
5.3.1 The BSO is a member of the BSL-3 Program Team;
5.3.2 Leads the review of project procedures as documented in the lab manual during periodic inspections or at least annually;
5.3.3 Leads the vulnerability & threat assessment process for select agent use;
5.3.4 Provides acceptance/cover letter to IBC for facility certification;
5.3.5 Participates in the development and review of facility-specific SOPs and other associated documents;
5.3.6 Assists with the development of a bio-security plan;
5.3.7 Investigates incidents of nonconformance and suspends access privileges if warranted;
5.3.8 Responds to and reports out (to all applicable parties) reported exposure or accidental release and documents with an incident report;
5.3.9 Leads the University select agent program and acts as the Responsible Official (RO);
5.3.10 Act as liaison with outside agencies (e.g., OSHA, EPA, CDC, NIH, USDA, etc.), attends regulatory inspections and close out meetings;
5.3.11 Assembles and leads the BSL-3 Advisory Committee (BAC);
5.3.12 Assists with the commissioning, annual verification, decontamination, and maintenance activities;
5.3.13 Investigates and assists with remediation of physical and operational failures (e.g., HVAC alarms);
5.3.14 Participates in the development and delivery of BSL-3 related training;
5.3.15 Acts as an informational resource for biosafety practices and procedures;
5.3.16 Leads and coordinates the development of emergency response procedures and activities and reviews procedures annually;
5.3.17 Assists with escorting of approved visitors;
5.3.18 Serves as a member of the IBC, BAC, and IACUC;
5.3.19 Participates in the GHS medical screening and surveillance requirements;
5.3.20 Is medically cleared and fit tested to wear the appropriate respirator.

5.4 BSL-3 Advisory Committee (BAC): An ad-hoc sub-committee of the IBC, organized by the BSO, which reviews BSL-3 applications and associated documentation (e.g., research SOPs).
5.4.1 The BAC will include at least two faculty members of the IBC, the BSL-3 Program Team, and a representative of GHS Occupational Medicine, as well as a member of IACUC and a CARE veterinarian if projects involve animal use; when additional technical expertise is needed, faculty members from outside the IBC may be included in a non-voting advisory role.
5.4.2 Perform risk assessment for proposed agents and activities;
5.4.3 Identifies appropriate space;
5.4.4 Makes recommendations to the IBC, and IACUC where applicable;
5.5 **BSL-3 Authorized Individual:** This individual is listed on an approved BSL-3 application and conducts BSL-3 research or diagnostic activities (including visiting scientists), or supports these activities (e.g., CARE and LAS animal care staff). Authorized individuals will comply with the following:

5.5.1 Participates in all program requirements (e.g., EHS basic training, BSL-3 training modules, GHS-Occ. Med., demonstration of proficiency);

5.5.2 Demonstrates understanding of the risks involved while undertaking BSL-3 work and demonstrates proficiency in BSL-3 procedures as required;

5.5.3 Supports BSL-3 Program Team with preparing lab for annual shutdown, Visitor escort and similar requests;

5.5.4 Complies with all University, regulatory requirements, and standard operating procedures (both research and facility specific SOPs) pertaining to the acquisition, manipulation, transfer, treatment and disposal of biohazardous materials, including samples, cultures, specimens and solid and liquid wastes;

5.5.5 Reports all accidents, injuries, exposures and/or releases, safety hazards or loss of materials to the principal investigator (PI) and a member of the BSL-3 Program Team;

5.5.6 Uses control measures such as engineering controls, biological safety practices, and personal protective equipment to minimize exposures to agents and contamination of personnel and facilities;

5.5.7 Participates in the GHS medical screening and surveillance requirements;

5.5.8 Reports changes in health status to GHS-Occupational Medicine;

5.5.9 Approved through the Animal Users Health and Safety Program (AUHSP) for animal facilities;

5.5.10 Is medically cleared and fit tested to wear the appropriate respirator, if applicable.

5.6 **BSL-3 Specialist (BSS):** Works closely with and supports the EHS Biosafety Officer and the CVM Biosafety Engineer for the implementation of the University BSL-3 program.

5.6.1 The BSS is a member of the BSL-3 Program Team;

5.6.2 Assists with the commissioning, annual performance verification, decontamination, and maintenance activities related to BSL-3 spaces;

5.6.3 Participates on new BSL-3 facility project teams as the EHS representative;

5.6.4 Investigates and assists with remediation of physical and operational failures (e.g., building and HVAC alarms);

5.6.5 Leads the review and revision of the program document as required;

5.6.6 Leads the development and review of facility specific standard operating procedures (SOPs) and other associated documents;

5.6.7 Leads the development and execution of a plan of action for new building/space occupancy;
5.6.8 Assists with review of lab specific biosafety manual annually;
5.6.9 Assists in risk assessments and evaluations;
5.6.10 Assists with incident response and investigations;
5.6.11 Participates in the development and delivery of BSL-3 related training;
5.6.12 Assists with emergency response activities;
5.6.13 Coordinates and conducts periodic inspection and review of ongoing activities, report’s findings to program team;
5.6.14 Participates in the development of bio-security plans;
5.6.15 Assists with approval of personnel for access to BSL-3 space;
5.6.16 Assists with escorting of approved Visitors;
5.6.17 Serves as a member of the BAC;
5.6.18 Participates in the GHS medical screening and surveillance requirements;
5.6.19 Is medically cleared and fit tested to wear the appropriate respirator.

5.7 BSL-3 Program Team: A Team of professionals that includes: the CVM Biosafety Engineer (BE), EHS Biosafety Officer (BSO) and EHS Biosafety Level Three Specialist (BSS) who work together to administer the University BSL-3 program in compliance with this written program. For specific roles and responsibilities of each team member please see above.

5.8 BSL-3 Steering Committee: A University level committee convened to oversee the implementation of the BSL-3 program. It is composed of the Associate Vice President for Research Administration, Directors of EHS and Occupational Medicine at Gannett Health Services, CVM Associate Dean for Research and Graduate Education, CVM Associate Dean for Veterinary Public Policy, the Chair of the IBC, the BE and BSS.

5.9 BSL-3 Visitor: Enters an active BSL-3 space, but does not undertake research or diagnostic activities within the space (e.g., maintenance personnel, IACUC inspector, state or federal regulator).
5.9.1 Visitors will comply with the following:
5.9.1.1 Performing activities supported by the PI (e.g., escorted walk through, maintenance);
5.9.1.2 Satisfies all requirements listed on the visitor access checklist;
5.9.1.3 Complies with all University and facility specific SOPs;
5.9.1.4 Is escorted into the BSL-3 space by a member of the BSL-3 Program Team (i.e., the Biological Safety Officer, Biosafety Engineer, or BSL-3 Specialist) or their designee;
5.9.1.5 Completes the AUHSP risk assessment form for animal facilities, if applicable;
5.9.1.6 Is medically cleared and fit tested to wear the appropriate respirator, if applicable.

5.10 Center for Animal Resources and Education (CARE): Is composed of veterinarians and veterinary technologists responsible for the care of animals used in research, and the education of faculty, staff and students on the responsible use of animals in research. See http://www.research.cornell.edu/care.

5.10.1 Provide animal care and veterinary services;
5.10.2 Advise on animal welfare and experimentation issues;
5.10.3 Conducts ABSL-3 user training, specifically animal handling and procedural techniques;
5.10.4 Provides training to LAS staff (e.g., module 2 for animals);
5.10.5 Develop and provide animal husbandry and related training;
5.10.6 Participates in the planning, design and approval of new construction or renovation (if an animal facility);
5.10.7 Select members serve on BAC, if applicable;
5.10.8 Select members act as Authorized Individuals in ABSL-3 spaces that use animals.
5.10.9 Participate in the GHS medical screening and surveillance requirements;
5.10.10 Are medically cleared and fit tested to wear the appropriate respirator.

5.11 CARE (Animal Services): Composed of professional care givers that have responsibility for animal husbandry and support services in areas that use animals.

5.11.1 Assure appropriate animal housing is available;
5.11.2 Approve animal orders and oversee animal husbandry;
5.11.3 Participate in applicable program elements (i.e., EHS basic training, BSL-3 training modules, demonstration of proficiency, medical screening surveillance, respiratory protection program, etc.);
5.11.4 Develop and provide animal husbandry and related training to authorized users;
5.11.5 Participate in the GHS medical screening and surveillance requirements;
5.11.6 Select staff serves as authorized individuals in BSL-3 spaces that use animals;
5.11.7 Are medically cleared and fit tested to wear the appropriate respirator.

5.12 Cornell University Police Department (CUPD): A group of armed peace officers who provide and maintain a safe and orderly learning environment in which to conduct activities. See http://www.cupolice.cornell.edu.

5.12.1 Participate in vulnerability and threat assessments for projects involving Select Agent use;
5.12.2 Assists with development of bio-security plan;
5.12.3 Respond to, and investigate security breaches, intrusion alarms, missing infectious agent concerns and other emergencies as required;
5.12.4 Members attend BSL-3 awareness training annually.

5.13 **EHS Emergency Services 2418 Group:** Employees of EHS who respond to facility and medical related emergencies. See [http://sp.ehs.cornell.edu/Pages/Home.aspx](http://sp.ehs.cornell.edu/Pages/Home.aspx)

5.13.1 Respond to fire alarms and other emergencies and follow up with BSL-3 Program Team as appropriate;
5.13.2 May provide emergency medical assistance;
5.13.3 Review the emergency response procedures annually with a member of the BSL-3 Program Team;
5.13.4 Participate in emergency response activities as the University incident commander for medical emergencies and spills;
5.13.5 Act as a liaison with other response agencies during emergency response (e.g., CU EMS, IFD, CUPD);
5.13.6 Members attend BSL-3 awareness training annually;
5.13.7 Are medically cleared and fit tested to wear the appropriate respirator.

5.14 **Facility Administrator:** Is responsible for providing operational support for facilities and spaces. This role may be performed by one or more individuals.

5.14.1 Responsible for space assignments, procurement of centrally-provided PPE and provision of data of appropriate accounting personnel for collection of user fees for BSL-3 laboratory spaces;
5.14.2 Posts HASP and restricted access signage;
5.14.3 Programs personnel approved by the BSL-3 Program Team into the facility’s access control system;
5.14.4 Support BSL-3 Program Team with response to nonconformance issues (e.g., by changing access rights as requested);
5.14.5 Assist the BSL-3 Program Team with maintenance-related activities.

5.15 **Gannett Health Services (GHS)-Occupational Medicine:** Is staffed by medical and nursing professionals that provide medical screening and surveillance for authorized users. See [http://www.gannett.cornell.edu/](http://www.gannett.cornell.edu/)

5.15.1 Maintain health evaluation data for employees;
5.15.2 Interface with applicable state entities regarding employee exposures and illnesses;
5.15.3 Develop partnerships with external health providers to monitor occupational health issues for employees and students;
5.15.4 Communicate occupational health issues with affected individuals and EHS staff as appropriate for follow-up;
5.15.5 Provide a confidential, post-exposure medical evaluation;
5.15.6 Notify the BSO of the exposure;
5.15.7 Select members serve on BAC.

5.16 Institutional animal Care and Use Committee (IACUC): Is a faculty based committee responsible for review and approval of activities involving animals used in research and compliance with applicable federal and state regulations and appropriate guidelines. See [http://www.iacuc.cornell.edu](http://www.iacuc.cornell.edu).
5.16.1 Provide oversight of the Animal Care and Use program;
5.16.2 Review and approve animal care & use protocols, amendments and related SOPs;
5.16.3 Perform semi-annual inspections of BSL-3 areas that involve housing or procedures with animals;
5.16.4 Authorize suspension and/or termination of animal protocols as deemed appropriate, and communicates such to the PI;
5.16.5 Members fulfill requirements for visitor access and AUHSP, if applicable;
5.16.6 If applicable, is medically cleared and fit tested to wear the appropriate respirator;
5.16.7 Select members serve on BAC as appropriate.

5.17 Institutional Biosafety Committee (IBC): Is a faculty based committee responsible for review and approval of activities involving biohazardous and recombinant DNA materials used in research or diagnostic activities. See [http://www.ibc.cornell.edu](http://www.ibc.cornell.edu).
5.17.1 Review and approve Memorandum of Understanding and Agreement (MUA), BSL-3 applications, and research-related SOPs;
5.17.2 Authorize suspension and/or termination of MUA and/or personnel access privileges as deemed appropriate, and communicates such to the PI;
5.17.3 Provide written approval and certification of a facility for use at BSL-3;
5.17.4 Advises the appropriate Departmental Chair of the suspension or termination of access privileges for individuals found to be in violation of the Cornell BSL-3 Program or related procedures governing the use of BSL-3 facilities;
5.17.5 Perform annual inspections of spaces;
5.17.6 Members fulfill requirements for visitor access and AUHSP, if applicable;
5.17.7 If applicable, are medically cleared and fit tested to wear the appropriate respirator;
5.17.8 Select members serve on BAC.

5.18 Institutional Official: Senior Vice Provost for Research who has oversight of research programs at Cornell.
5.18.1 Commit that the University will meet federal, state and University requirements related to BSL-3;
5.18.2 Sign reports and letters on behalf of the University;
5.18.3 Reports out, in writing, to state and federal agencies as required.

5.19 Office of Research Integrity and assurance (ORIA): Is responsible for ensuring that research conducted on the Cornell Ithaca campus is in accordance with University policies and applicable external regulations and guidelines.
5.19.1 Responsible for managing, supporting, monitoring, and assessing Cornell’s research compliance programs;
5.19.2 Maintain a secure database with registration of documents on research or diagnostic activities;
5.19.3 Archive all records (typically for 7-10 years) that pertain to decisions and actions of the IBC;
5.19.4 Notify the Principal Investigator (PI) of the results of the IBC/IACUC review;
5.19.5 Act as liaison with outside research funding agencies (e.g., NIH, USDA);
5.19.6 Report exposure or accidental release to appropriate federal and state regulatory agencies;
5.19.7 Communicate to PI deliberations regarding suspensions or termination of MUA or IACUC protocol;
5.19.8 Facilitate the reporting of non-compliances to internal and external agencies, as appropriate.

5.20 Principal Investigator (PI): Is an individual who has the responsibility for the design and implementation of research that uses infectious or biohazardous materials.
5.20.1 Responsible for the development and implementation of research SOPs;
5.20.2 Ensure that personnel participate in all BSL-3 program elements (i.e., EHS basic training, BSL-3 training modules, demonstration of proficiency, agent specific medical screening and surveillance, respiratory protection program, etc.);
5.20.3 Identify users and determine suitability, with input from the BSO and GHS, to work at BSL-3;
5.20.4 Consult with the BSL-3 Program Team, facility manager and CARE as appropriate;
5.20.5 Ensure reporting of all accidents/incidents involving their staff through the Cornell University Injury/Illness Report system within 24 hours;
5.20.6 Report accidental release or exposure to the environment to the BSO or ORIA within 24 hours;
5.20.7 Maintain documents (i.e., permits, records, material transfer agreements, research SOPs, log book, etc.);
5.20.8 Monitor the health and safety, and performance of personnel under his/her supervision;
5.20.9 Maintain an updated list of infectious or biohazardous materials with documented material transfers;
5.20.10 Ensure lab equipment is working properly and maintained as recommended;
5.20.11 Complete the BSL-3 application and MUA, IACUC protocol, if applicable, obtain respective committee approvals, and submit amendments to IBC and IACUC when appropriate;
5.20.12 Procurement of infectious agents;
5.20.13 If applicable, completes appropriate training and demonstrates proficiency;
5.20.14 If applicable, participates in the GHS medical screening and surveillance requirements;
5.20.15 If applicable, is medically cleared and fit tested to wear the appropriate respirator.

6.0 Elements of the BSL-3 Program

6.1 Program Administration

6.1.1 Application and Amendment Process

6.1.1.1 To facilitate the BSL-3 application process, the PI will engage with the BSL-3 Program Team prior to submitting their application;

6.1.1.2 The investigator will have a new or existing MUA with the IBC. If animals will be used, the investigator will have an animal use protocol with IACUC;

6.1.1.3 The investigator will complete a BSL-3 application that describes the specific hazards and experiments, personnel, and the resources required to conduct activities at BSL-3 (refer to BSL-3 workflow process diagram presented in Appendix A)

6.1.1.4 If an amendment, the PI will notify the IBC Administrator directly.

6.1.1.4.1 The IBC Administrator will return the most recently approved registration to the PI.

6.1.1.4.2 The PI will amend this document and return to the IBC Administrator.

6.1.1.4.3 The IBC Administrator will note the changes to the document and notify the BSO for determination of appropriate action (in consultation with the BSL-3 program team and IBC chair when appropriate).

6.1.1.4.4 The BSO notifies the BAC and requests a review via email or in person (BSO decides). Note if email is used, BAC members must use the “reply to all” function when sending comments.

6.1.1.4.5 Significant changes (i.e., change in project scope, or agent, work includes rDNA) will require review and approval by the full IBC with recommendations from the BAC. Minor changes (i.e., personnel, location, work with rDNA is not involved) can be approved administratively outside the full IBC with recommendation from the BAC and IBC Chair.

6.1.1.5 The BSO will assemble the BSL-3 Advisory Committee (BAC), which will review the BSL-3 application and supporting information such as research SOPs;

6.1.1.6 The BAC review and risk assessment process will evaluate:

6.1.1.6.1 The proposed scientific activities and the suitability of the project for BSL-3;
6.1.1.6.2 Control measures (engineering, work practices, personal protective equipment, etc.) to mitigate risks of proposed activities;
6.1.1.6.3 Occupational health and medical surveillance concerns;
6.1.1.6.4 Animal or plant health issues, and agricultural and environmental risks, if applicable;
6.1.1.6.5 The suitability of the available BSL-3 facilities for the proposed work.

6.1.1.7 The BSO collects feedback on behalf of the BAC and drafts a response (to include recommendations, modifications, condensing, etc.).

6.1.1.8 The BSO sends a draft summary response to the BAC for final review and comment.

6.1.1.9 The BSO sends the final response to the IBC Administrator.

6.1.1.10 The IBC Administrator sends the final response to the PI.

6.1.1.11 The PI will return the revised document (if required) to the IBC Administrator.

6.1.1.12 The IBC Administrator will distribute the revised documents to the BAC.

6.1.1.13 At time of approval, the IBC Administrator will save the document with approved date, archive and send copy to the PI.

6.1.1.14 The BSO (or their designee) will present the results of the BAC review to the IBC.

6.1.1.15 The IBC will use the BAC assessment and information from the Institutional Animal Care and Use Committee (IACUC) review, if applicable, in its evaluation of the BSL-3 application for approval.

6.1.1.16 The IBC will communicate the approval status to the PI.

6.1.1.17 Once approved, the investigator will work with the appropriate facility administration and the BSL-3 Program Team to secure space, equipment, and animals, if applicable.

6.1.1.18 Changes to standard operating procedures (SOPs) will be reviewed and approved before implementation. Significant changes to SOPs, addition of agents or modifications to approved applications or IACUC protocols will first be approved by the IBC and IACUC, respectively. The PI will notify a member of the BSL-3 Program Team of minor changes that do not significantly impact containment or alter personnel exposure risks to determine whether the change(s) should be reviewed and approved by the BAC.

6.1.2 Records and Documentation

6.1.2.1 Each BSL-3 laboratory will maintain a biosafety manual (at the entry point, e.g., anteroom, and inside the lab) that defines the function and operation of that laboratory. The manual will include:

6.1.2.1.1 Research-specific SOPs
6.1.2.1.2 Facility-specific SOPs
6.1.2.1.3 Animal-specific SOPs, if applicable
6.1.2.1.4 BSL-3 application
6.1.2.1.5 BSL-3 space access approval checklists
6.1.2.1.6 BSL-3 program document
6.1.2.2 Each investigator’s BSL-3 laboratory specific biosafety manual, developed with assistance from the BAC and the BSL-3 Program Team, will be reviewed, at least annually, by the BSO or his/her designee.
6.1.2.3 Users at each BSL-3 facility will maintain log books that document the entry and exit of individuals from the space and facility intended activities and any adverse incidents. Copies of the access approvals checklist are also included in the log book.
6.1.2.4 Users will maintain forms on site (e.g., in the anteroom or vestibule) that document the receipt, transfer and movement (e.g., bill of lading) of biohazardous materials to and from the BSL-3 facility.
6.1.2.5 Investigators will provide the IBC with copies of permits required by the CDC or USDA/APHIS for the shipment, possession, and use of infectious agents.

6.1.3 Training and Proficiency
6.1.3.1 Principal investigators, laboratory directors, and authorized users will be knowledgeable about the agent, duties necessary to carry out activities, procedure associated hazards, and animal use, if applicable.
6.1.3.2 The Principal Investigator, BAC and the BSL-3 Program Team will evaluate an individual’s qualifications to engage in activities at BSL-3.
6.1.3.3 Individuals who will engage in BSL-3 activities will complete EHS basic training modules (e.g., lab safety, Bloodborne pathogens) and participate in a BSL-3-specific training program that can include classroom and hands on components such as:
   6.1.3.3.1 The concept of containment at BSL-3
   6.1.3.3.2 Occupational medicine related issues for the agent in question
   6.1.3.3.3 Facility orientation and building alarms
   6.1.3.3.4 General precautions to prevent or minimize exposures
   6.1.3.3.5 Donning/doffing of personal protective equipment (PPE)
   6.1.3.3.6 Entry/exit procedures
   6.1.3.3.7 Working in a biosafety cabinet (BSC)
   6.1.3.3.8 Facility and personal emergencies
   6.1.3.3.9 Daily operational activities
   6.1.3.3.10 Decontamination
6.1.3.3.11 Waste and spill procedures
6.1.3.3.12 Animal handling procedures and emergencies (if applicable)
6.1.3.3.13 See the access requirements checklist

6.1.3.4 If respiratory protection (OSHA Respiratory Protection Standard, 29 CFR 1910.134) is required, individuals will be medically cleared by GHS, Occupational Medicine, and receive fit testing and training by EHS.

6.1.3.5 Each trained individual will exhibit understanding through hands on demonstration and proficiency of key activities (e.g., use of biosafety cabinet, entry/exit procedures, donning/doffing of PPE) and/or written examination prior to gaining entry to BSL-3 spaces and conducting activities.

6.1.3.6 The BSL-3 Program Team and their designees (e.g., Occupational Medicine staff, CARE/LAS staff) will provide and supervise the training and proficiency.

6.1.3.7 Before an individual is allowed to work unsupervised, they will work under the supervision of an experienced authorized individual or a member of the BSL-3 Program Team until the person demonstrates competency.

6.1.3.8 Annual refresher training will be required (e.g., a hands on exercise regarding relevant topic). Additional training may be required when new biohazardous materials, procedures, or animal systems are introduced.

6.1.3.9 Visitors who enter an active BSL-3 space will first receive an orientation from a member of the BSL-3 Program Team or their designee that should discuss:
6.1.3.9.1 Donning/doffing of personal protective equipment (PPE)
6.1.3.9.2 Entry/exit procedures
6.1.3.9.3 Emergency procedures
6.1.3.9.4 The AUHSP program, if animals are used

6.1.3.10 Visitors will be accompanied at all times during the visit. In animal facilities, the animal facility manager or designee will accompany visitors.
6.1.3.10.1 Active BSL-3 Spaces: Visitors (e.g., equipment service technicians, visiting scientists) must comply with the same respiratory protection requirements as Authorized Users when entering active (i.e., “hot”) BSL-3 spaces. If respiratory protection is required, visitors must comply with the OSHA Respiratory Protection Standard, 29 CFR 1910.134. Visitors who are not Cornell employees are required to provide their own respirators.
6.1.3.10.2 Inactive BSL-3 Spaces: For inactive BSL-3 spaces (i.e., spaces that have been shut down and decontaminated) respirator use will be voluntary. The BSL-3 Program Team will provide
information on the decontamination method and results to the visitors so they can determine their personal protective equipment (PPE) needs. Visitors who are not Cornell employees are required to provide their own respirators.

6.1.4 Use of Select Agents and Toxins

6.1.4.1 In addition to requirements outlined in this program document, individuals planning to include select agents and toxins (http://www.selectagents.gov/Select%20Agent%20and%20Toxins%20List.html) in their BSL-3 activities will first consult with the BSO.

6.1.4.2 The BSO, acting as the RO for the University’s select agent program, will facilitate the completion of security risk assessments with the U.S. Department of Justice, and amend the University’s registration document with the USDA/CDC to reflect changes in personnel, agents, and facilities.

6.1.4.3 Additional security measures (e.g., access control, storage) and select agent-specific training will be in place before activities commence.

6.1.5 Reviews and Inspections (Work Practices and Assessment)

6.1.5.1 The BAC will perform an initial risk assessment, before activities commence, which will assess research SOPs, training, work practices and procedures, and suitability of engineering controls and personal protective equipment (PPE).

6.1.5.2 A member of the BSL-3 Program Team will perform periodic onsite reviews at active BSL-3 operations and report out as necessary.

6.1.5.3 If animals are used in research, authorized members of the IACUC (e.g., BSO, CARE veterinarian) or IACUC visitors accompanied by an authorized individual will perform semi-annual inspections of laboratory/animal spaces as part of the animal care and use program.

6.1.5.4 At least annually, the BSO/BSL-3 Program Team will provide a review of active BSL-3 operations to the IBC.

6.1.6 Nonconformance

6.1.6.1 Nonconformance is defined as the failure or refusal to comply with the requirements described in this document or facility-specific SOPs, or the conduct of unsafe practices.

6.1.6.2 Incidents of nonconformance can be directly observed and reported to the BSL-3 Program Team, IBC, or Ethicspoint (1-866-293-3077, www.hotline.cornell.edu). Incidents of nonconformance can also be self-reported.
6.1.6.3 A tiered approach will be utilized to investigate potential incidents of nonconformance. The tiers are based on severity of the incident with proposed guidance for the level of response by the appropriate biosafety professional.

6.1.6.4 The IBC has the authority to suspend or terminate BSL-3 activities of a given PI or project as a result of nonconformance with requirements outlined in this document or under IBC jurisdiction.

6.1.6.5 The BSO (or their designee) will document confirmed incidents of nonconformance and their resolution, and periodically give verbal summary reports to the IBC and BSL-3 Steering Committee.

6.1.6.6 Incidents of nonconformance will be managed in a progressive manner as described below:

6.1.6.6.1 Tier 1: For situations that impact the individual only. Upon observation or receipt of a confirmed report of nonconformance, the BSO (or their designee) will immediately notify the involved individual and identify appropriate corrective actions. If the nonconformance is corrected immediately, the BSO (or their designee) will document the nonconformance and promptly notify/copy other BSL-3 Program Team members and send a written notification of conformance to the involved individual. No further action will be taken if the incident is promptly resolved.

Examples of Tier 1 nonconformance include, but are not limited to:
- Improper use of Personal Protective Equipment (e.g., wearing an N95 respirator without being clean shaven, failure to wear eye protection, or not re-gloving per SOPs)
- Recapping needles
- Failure to report an exposure or injury.
- Failure to comply with access requirements (e.g., annual training, respirator fit test).
- Nonconformance with entry procedures (e.g., failure to log in/out, “piggybacking” through main entry point doors.)

Resolution of a Tier 1 nonconformance requires that the involved user(s) correct the nonconformance immediately. The BSO (or their designee) will document that the incident has been satisfactorily resolved.

6.1.6.6.2 Tier 2: Tier 2 includes unresolved Tier 1 nonconformances and nonconformances that could impact others inside the BSL-3 space or that could result in a release outside the BSL-3 space. The BSO (or their designee) will provide written documentation of the incident to the individual and to the PI with a copy to others (e.g., other building occupants as appropriate).

Examples of Tier 2 nonconformance that could impact others include, but are not limited to:
- Improper agent transportation practices
- Improper chemical/container labeling
- Failure to follow Biological Safety Cabinet (BSC) procedures
- Improper decontamination of work surfaces
- Failure to report a spill of infectious agent outside of primary containment but within the BSL-3 space
- Failure to follow waste disposal procedures (i.e., incorrect autoclave cycle time, improper waste container use, mishandling of waste bags)
- Improper PPE doffing practices
- Actions that compromise physical security of the facility
- Allowing entry to BSL-3 space by unauthorized persons.

Resolution of Tier 2 nonconformance requires that the PI address the nonconformance directly with the involved user(s) and ensure that it is corrected immediately, and provide a written description to the BSO (or their designee) of actions taken by the PI and individual to correct the issue, and that the involved user(s) participate in re-training in the areas of nonconformance.

6.1.6.6.3 Tier 3: Tier 3 includes unresolved Tier 2 nonconformances and nonconformances where an action results in immediate danger to users of the BSL-3, persons outside the BSL-3, or the environment.

Examples of Tier 3 nonconformance include, but are not limited to:
- Unreported spill of infectious materials outside of containment
- Failure to wear critical PPE (e.g., no respirator or bare hands)
- Any criminal activity associated with the BSL-3 (e.g., theft, physical or verbal threats)
- Intentional bypass of equipment safety features
- Unreported equipment malfunctions that could pose a significant hazard (e.g., autoclave high pressure safety devices).

The BSO (or their designee) will provide written and verbal communication regarding the incident directly to the Chair of the IBC, as well as a formal notification to the PI, with a copy to their Department Chair and respective College Administration. If a nonconformance is not resolved at Tier 3 within a reasonable time frame (e.g., 48 hours), the BSO (or their designee) will suspend access rights for the involved individual(s).
Access rights will remain suspended until the Chair of the IBC approves a report from the BSO (or their designee) detailing that the nonconformance has been adequately addressed (including the PI reporting requirement described under Tier 2).

Examples of corrective actions will include, however, are not limited to:
- Re-training
- Repeat proficiency demonstration
- Direct observation and supervision by the PI
- Limiting the number of users allowed working in the BSL-3 simultaneously

Resolution of Tier 3 nonconformance:
Resolution of Tier 3 nonconformance requires that the PI address the nonconformance directly with the involved user(s) and ensure immediate correction and that the PI provide a written description to the BSO (or their designee) of actions taken by the PI and individual to correct the issue. The involved user(s) must participate in re-training and comply with other corrective actions as determined by the BSO (or their designee).

6.1.6.6.4 Tier 4: *Tier 4 results when an individual(s) repeats the same Tier 3 nonconformance after re-instatement of access, if the PI fails to adequately address a Tier 3 nonconformance, or if an individual has multiple instances of nonconformance at one or more levels.* The BSO (or their designee) will suspend access rights for the involved individual(s) and provide written and verbal communication regarding the incident directly to the Chair of the IBC. The IBC Chair will provide written notification to the individual and the PI, with copies to their Department Chair, respective College Administration, and ORIA. The nonconformance and resulting corrective actions, including suspension or revocation of user access and/or the IBC’s approval for the project, will be determined by the full IBC.

6.1.6.7 Nonconformance with Occ. Med requirements: Communication regarding requirements for the medical surveillance program will include the following:

6.1.6.7.1 GHS-OM will contact individuals (email, letter, or phone call) requesting that they make an appointment. For follow-up surveillance, this communication is initiated at least 30 days prior to due date.

6.1.6.7.2 If an individual does not respond within two weeks of the initial communication, GHS-OM sends an email or letter to the individual with a copy to the supervisor.
6.1.6.7.3 If an individual does not respond within two weeks of the second notice, GHS-OM sends a letter to the BSO (or their designee) recommending follow up as a Tier 2 nonconformance.

6.2 Facilities

6.2.1 Design, Construction, Certification, and Performance Verification

6.2.1.1 Design

6.2.1.1.1 The BE, with support from the BSO and the BSS, together with involved PIs and representatives from CARE if an animal facility or procedure area is to be constructed, will participate in the planning design, and approval of new BSL-3 design guidelines. The BSO and BE may enlist the expertise of consultants both inside and outside Cornell University.

6.2.1.1.2 All Cornell BSL-3 facilities will comply with the most current standards and/or guidelines from the University and other agencies such as CDC, USDA, and AAALAC.

6.2.1.2 Construction (including commissioning)

6.2.1.2.1 Approval will be sought from the BSO and BE, plus CARE if animal facility, for any containment related design changes occurring during construction of BSL-3 facilities.

6.2.1.2.2 The BSL-3 Program Team will participate in the commissioning process to ensure that the BSL-3 facility can be operated as intended. During the project’s commissioning phase, the BSL-3 Program Team will perform additional testing of the BSL-3 facility to fulfill the requirements of the team’s annual performance verification testing exercises.

6.2.1.3 Certification and Performance Verification

6.2.1.3.1 The BSO and BE, plus CARE if an animal facility, will provide written confirmation of a BSL-3 facility’s commissioning and initial performance verification to the IBC and IACUC, if applicable.

6.2.1.3.2 Written approval by the IBC and IACUC, if applicable, is required before a facility can operate at BSL-3.

6.2.1.3.3 The BSL-3 Program Team will periodically verify and document the performance of all BSL-3 facilities’ HVAC systems, alarms, and other containment features. Verification exercises will be conducted at least annually.

6.2.2 Space Allocation
6.2.2.1 During the BSL-3 application review process, once the BAC has determined that BSL-3 containment is required, it will determine the suitability of existing Cornell BSL-3 facilities for the proposed BSL-3 project based on a risk assessment that will include consideration of the engineering controls and other features at each facility.

6.2.2.2 Once the BSL-3 project is approved by the IBC, the project’s Principal Investigator will request a room assignment from the Facility Administrator of the BSL-3 facilities approved for the project by the IBC.

6.2.2.3 In situations where the space in a BSL-3 facility is limited or unavailable (e.g., more than one project requesting use of one space), final determinations of space allocation will be made as follows:

6.2.2.3.1 For the ECRF ABSL-3 facility, final determination will be made by the director of CARE based on a recommendation by the Cornell BSL-3 Steering Committee or an ad-hoc faculty committee.

6.2.2.3.2 For the research BSL-3 suite at the NYS Veterinary Diagnostic Laboratory (VDL) facility, the Dean of the CVM will make the final determination based on a recommendation by the Cornell BSL-3 Steering Committee or an ad-hoc faculty committee.

6.2.2.3.3 For the BSL-3 laboratories in the Veterinary Medical Center and the R&D Annex (building 1780) BSL-3 facility, the Dean of the CVM will make the determination.

6.2.3 BSL-3 Infrastructure Management

6.2.3.1 BSL-3 infrastructure includes BSL-3 HVAC systems and associated controls and indicators (e.g., pressure gauges), autoclaves and other waste decontamination systems, biological safety cabinets (BSCs) and related primary containment equipment, and fumigation equipment. The BE will lead (with backup from the BSS, BSO, and support from the CVM Facilities Administration Office and Cornell Shops) the management of BSL-3 infrastructure elements, response to HVAC alarms, verification of autoclave performance, and fumigation of BSL-3 spaces and equipment.

6.2.3.2 Maintenance

6.2.3.2.1 Access to BSL-3 spaces by maintenance personnel (including Cornell employees, contractors, and equipment manufacturer’s technicians) is restricted; maintenance personnel may only enter BSL-3 spaces under escort from a member of the BSL-3 Program Team or their designee, unless the facility has been decontaminated and released for access by a member of the BSL-3 Program Team.

6.2.3.2.2 Routine preventative maintenance of BSL-3 infrastructure will typically be performed during shutdowns of BSL-3 spaces after the space(s) has been completely decontaminated.
Where complete shutdowns and decontaminations are not feasible, the preventative maintenance will be performed during periods of no scientific activity in the space to minimize risks to maintenance personnel, and maintenance personnel will wear PPE as directed by a member of the BSL-3 Program Team.

6.2.3.2.3 Non-routine maintenance of BSL-3 infrastructure will be performed as needed without complete shutdown and decontamination of the space. In those situations, the maintenance will be performed during periods of no scientific activity in the space to minimize risks to maintenance personnel, and maintenance personnel will wear PPE as directed by a member of the BSL-3 Program Team.

6.2.3.3 HVAC Alarm response

6.2.3.3.1 HVAC alarms will be communicated automatically to the Cornell Energy Management Control System (EMCS) operations center by building automation systems. Alarms can also be called in to EMCS by personnel at BSL-3 facilities.

6.2.3.3.2 The EMCS operator on duty will attempt to contact a member of the BSL-3 program team (in order of the BE, BSS, and then the BSO), the building coordinator, or the PI per the emergency call list for the facility.

6.2.3.3.3 The BSL-3 program team member or the building coordinator will coordinate with the facility users, the EMCS operator, and maintenance personnel as appropriate to respond to the alarm.

6.2.3.3.4 BSL-3 users will respond to HVAC alarms per the appropriate facility-specific SOP and report them immediately to the facility administrator and a member of the BSL-3 program team. Activities within the BSL-3 space will be suspended during HVAC alarms until re-authorized by a member of the BSL-3 program team.

6.2.3.4 Autoclave Verification

6.2.3.4.1 Proper operation of autoclaves at BSL-3 facilities will be verified through periodic (at least quarterly) challenge cycles with biological indicators by the BSL-3 Program Team.

6.2.3.4.2 Records of autoclave testing will be maintained for at least one year.

6.2.3.5 Decontamination

6.2.3.5.1 BSL-3 spaces will be decontaminated by the BSL-3 Program Team as part of periodic shutdowns for preventative maintenance and/or performance verification exercises.
6.2.3.5.2 BSL-3 spaces may also be decontaminated as part of the response to spills or other accidents, or when projects are moving out of the BSL-3 laboratories or animal rooms in the facilities as determined appropriate by the BSL-3 Program Team.

6.2.3.5.3 Unless determined otherwise by the BSL-3 Program Team in response to case-specific needs, space decontamination will be performed by fumigation with vapor-phase hydrogen peroxide or another suitable disinfectant.

6.2.3.5.4 Large equipment items (e.g., BSCs and freezers) may be decontaminated for removal from a BSL-3 space for maintenance or replacement. In such cases, the decontamination by hydrogen peroxide fumigation will be performed by the BSL-3 Program Team during a period of inactivity in the BSL-3 space.

6.2.3.5.5 Management of any decontamination equipment will be performed by the BE.

6.2.3.5.6 Management of gas detection equipment will be performed by the BSS or other responsible parties at EH&S.

6.2.4 Facility Administration

6.2.4.1 Administration of BSL-3 facilities includes space assignments within a facility, procurement of centrally-provided PPE, recovery of associated costs, posting appropriate signage, and programming personnel approved by the BSL-3 Program Team into the facility’s access control system.

6.2.4.2 Facility administration for each facility will be performed as follows:

- 6.2.4.2.1 New York State Veterinary Diagnostic Laboratory (NYSVDL) Diagnostic BSL-3 laboratories: NYSVDL Administration
- 6.2.4.2.2 NYSVDL Research BSL-3 Suite: BE/CVM Biosafety Program
- 6.2.4.2.3 East Campus Research Facility (ECRF) ABSL-3 Suite: Lab Animal Services
- 6.2.4.2.4 Research & Diagnostic Annex (building 1780) BSL-3 Facility: BE/CVM Biosafety Program
- 6.2.4.2.5 Veterinary Medical Center (VMC) C5-126 (TB Lab): Department of Microbiology and Immunology Administration

6.2.4.3 Where PPE is centrally provided, facility administrators will procure and maintain inventories of PPE and recover costs associated with the PPE from the facility users, as appropriate.

6.2.4.4 Signage

- 6.2.4.4.1 A universal biohazard symbol will be posted at the entry to each BSL-3 space.
- 6.2.4.4.2 A HASP sign (Hazard Assessment Signage Program) will also be posted at the entry to each BSL-3 suite or space. This sign may also indicate additional hazards that may be
present within the lab space such as compressed gases, cryogenic liquids or flammable solvents.

6.2.4.4.3 In suites of BSL-3 spaces, a HASP sign will be posted at the entrance to each space if the agents, other hazards, or Principal Investigators are different than for the entire suite.

6.2.4.5 Facility administrators will maintain the list of approved users in their facility’s access control system, in cooperation with the BSL-3 Program Team; administrators will only grant access to those authorized users approved by the BSL-3 Program Team and to the members of the team. For select agent spaces, this function will be performed by the BSO, acting as the RO.

6.2.5 Laboratory Security

6.2.5.1 BSL-3 spaces will be separated from areas open to unrestricted traffic by a series of at least two self-locking doors.

6.2.5.1.1 Access to the outer door of BSL-3 spaces (e.g., at the anteroom, locker room, or central corridor) will be controlled by a card reader lock. The BSL-3 Program Team will maintain a list of approved users for each facility and will communicate with responsible persons as appropriate.

6.2.5.1.2 Individual laboratories and animal rooms within a BSL-3 suite will have a dedicated card reader lock (i.e., authorized individuals will only be provided access to the laboratory spaces in which they have been approved for work).

6.3 Operations

6.3.1 Work Practices

6.3.1.1 Personnel will use safe work practices that are described in standard operating procedures approved by the IBC and are aligned with those practices described in the most recent version of the CDC/NIH publication “Biosafety in Microbiological and Biomedical Laboratories” and “NIH guidelines for Research Involving Recombinant DNA Molecules”.

6.3.1.2 The PI will develop SOPs that describe specific research or diagnostic processes to be used in the BSL-3 laboratory and the use of equipment that support those processes. These SOPs will be reviewed by the BAC/IBC prior to implementation and all personnel conducting research or diagnostic activities in a particular BSL-3 space are expected to follow these SOPs.

6.3.1.3 The BSL-3 Program Team is responsible for the development of facility-specific SOPs that describe commonly-used procedures (e.g., entering and exiting a facility, donning and doffing of PPE, use of the biosafety cabinet, and waste disposal) as well as emergency-related procedures (e.g., spill, fire, and HVAC alarm response).
6.3.1.4 New or modified procedures that differ significantly (e.g., potential impact to safety of operations, increase personnel exposure) from those described in approved SOPs will be reviewed by the BAC and approved by the IBC prior to implementation. Minor modifications to existing SOPs will be reviewed by the BSL-3 Program Team.

6.3.1.5 Personal electronic devices such as cellular phones, music players and cameras not dedicated to the BSL-3 space are not allowed in a BSL-3 space.

6.3.1.6 Data should be transferred outside the facility via dedicated computer and fax machines located within the BSL-3 space. Tablet computers contained in protective cases may be used, provided they can be immersed in a disinfectant solution. Papers (including printouts, hand notes or paper photographs), computer flash drives, hard discs, or notebook computers etc. may not be removed from within any BSL-3 space without being fumigated.

6.3.2 Equipment

6.3.2.1 Manipulation of live agent will take place within a biosafety cabinet or other primary containment device that uses HEPA filtration unless otherwise approved by the IBC.

6.3.2.2 HEPA-filtered devices will be certified semi-annually in conformance with “NSF/ANSI 49-2009 and Field Certification; Design, Construction, Performance and Field Certification” by a certified contractor. Scheduling of the certification is through the CVM Facilities Office, coordinating with facility users and the BSL-3 Program Team.

6.3.2.3 The PI is responsible for assessing that equipment in the laboratory is working properly and maintained as recommended, including facility-provided equipment, such as centrifuges and incubators. The animal facility manager will be responsible for animal related equipment (e.g., caging systems) used in animal rooms.

6.3.2.4 An autoclave for waste decontamination will be available at all BSL-3 facilities, preferably as a pass through device inside containment. Notification of a malfunctioning autoclave will be made to the CVM Facilities Office as soon as possible after identification of a problem.

6.3.2.5 The BSL-3 Program Team will be responsible for verifying proper operation of all autoclaves through periodic (at least quarterly) challenge cycles with biological indicators. Records of such testing will be maintained by the BSL-3 Program Team for at least one year.

6.3.2.6 Equipment that will be removed from a BSL-3 facility will first be decontaminated. The decontamination process will be reviewed and/or performed by the BSL-3 Program Team before removal from the facility.

6.3.3 Personal Protective Equipment
6.3.3.1 Personnel will be required to wear personal protective equipment (PPE) when entering and working within a BSL-3 facility. Minimum PPE will include institutional clothing (e.g., scrubs), gloves, disposable outer protective garments, and protective eyewear. The BAC and BSL-3 Program Team will perform a risk assessment to identify PPE components suitable for the agent, facility, and animal, if applicable (e.g., respiratory protection).

6.3.3.2 Individuals will be trained by the BSL-3 Program Team and demonstrate proficiency in the proper PPE donning, doffing, and decontamination, if applicable.

6.3.3.3 An individual who is required to wear respiratory protection will be enrolled in the University’s respiratory protection program and comply with the components of the OSHA respiratory standard, 29 CFR 1910.134. Components of this program include a medical evaluation by GHS, Occupational Medicine, and fit testing and training by EH&S.

6.3.4 Procurement and Movement of Biohazardous Materials

6.3.4.1 The PI may need a CDC, USDA-APHIS permit for receipt or movement of infectious agents or biohazardous materials. Additionally the PI may need a Material Transfer Agreement with the Office of Sponsored Programs if biohazardous materials are obtained from sources external to Cornell University (e.g., ATCC, collaborators at other institutions).

6.3.4.2 All transportation of materials in and out of BSL-3 facilities will comply with Cornell University and U.S. Department of Transportation shipping requirements including training for the shipper/transporter and documentation of the shipment/transfer. Documentation, including any dangerous goods paperwork and bills of lading, will be filed at the receiving BSL-3 facility in a designated notebook.

6.3.5 Access Control

6.3.5.1 Routine entry into BSL-3 spaces is restricted to authorized individuals and visitors escorted by a member of the BSL-3 Program Team or their designee.

6.3.5.2 Each authorized individual will independently activate the programmed access control system (e.g., ID card, key pad, biometric device). No “piggybacking” is permitted as a means of gaining entry to the main entrance of a BSL-3 suite. The BSL-3 Program Team is responsible for working with the respective facility administration to acquire facility keys, program ID cards and other access devices for authorized individuals. Authorized individuals will only be provided access to the laboratory spaces in which they have been approved for work.

6.3.5.3 Emergency access to a BSL-3 facility by EHS 2418 emergency responders or CU Police is via an emergency override key. Emergency responders will notify a member of the BSL-3 Program Team if entry is made into a BSL-3 facility.
6.3.5.4 Authorized individuals, including visiting scientists, will complete the items outlined in the access requirements checklist, including training, proficiency testing, clearance by Occupational Medicine, approval by the PI, and animal-related training, if applicable, prior to gaining programmed access. The BSL-3 Program Team will review and approve the requirements checklist.

6.3.5.5 Visitors may enter a BSL-3 space only for an activity approved by the PI and when accompanied by a member of the BSL-3 Program Team or their designee. When possible the visit will be scheduled when active work with live agents is not occurring. Visitors will receive a facility briefing that describes the nature of the work conducted in the facility, risks of exposure, PPE donning and doffing, and emergency procedures.

6.3.5.6 If respiratory protection is required, Cornell University visitors will be cleared by GHS, Occupational Medicine. Visitors who are not Cornell employees must comply with the respiratory protection requirement for entry into the space.

6.3.5.7 A personnel logbook is located at the entrance to each BSL-3 facility. All personnel will log their name, date and time of entry/exit, specific location, purpose of entry and any adverse incidents and “near misses”.

6.3.5.8 Lost or stolen cards or keys will be reported to the BSL-3 Program Team and Cornell Police.

6.4 Emergency Response

An emergency is defined as an incident that impacts personal health and safety, involves the release of biohazardous materials, or compromises the integrity and safety of the BSL-3 space or facility.

6.4.1 The type of emergency will define the urgency in reporting and the appropriate reporting mechanism. The following life threatening incidents require an immediate call to 911: a medical crises, serious personal injury, and threat to personal safety, fire, or gas leak. When possible 911 notifications to Cornell University Police (CUPD) should be initiated via a landline facility phone (alternately, 255-1111 from a cell phone). CUPD will alert the appropriate emergency response agencies (e.g., EHS 2418, CUPD, Ithaca Fire Department, and Bangs ambulance).

6.4.2 Other less urgent emergencies, including the release of infectious materials outside of primary containment (resulting in potential exposure), or room pressure failure in the laboratory, will be reported as soon as possible, but no later than 24 hours, to a member of the BSL-3 Program Team and the PI or laboratory director. All (even minor) personal injuries and exposures will be reported additionally to Gannett Health Services, Occupational Medicine, as soon as possible, but no later than 24 hours, and complete an online Injury/Illness/Exposure report (https://cfp-isca.cit.cornell.edu/accinj/).

6.4.3 Authorized individuals will follow the steps outlined in the facility-specific emergency response SOPs (e.g., exposures and injuries, fire alarms, HVAC alarms). When reporting emergencies, individuals will identify
themselves, nature and location of the emergency, any injuries or additional hazards, actions taken, and call back number.

6.4.4 Emergency responders will follow procedures outlined in the appropriate facility-specific SOP, according to the nature of the emergency (e.g., fire alarm vs. medical).

6.4.5 Releases of biohazardous materials, breaches of containment, or personal exposures may require reporting to internal (e.g., IBC, ORIA, Research Office) and external (e.g., CDC, USDA, NYSDOH) agencies. The BSO along with ORIA and the Institutional Official will determine outside reporting requirements and prepare communications to the appropriate parties.

6.5 Occupational Medicine and Exposure Response

6.5.1 Occupational Medicine for BSL-3

6.5.1.1 All authorized individuals will participate in the BSL-3 medical screening and surveillance program administered by Gannett Health Services-Occupational Medicine (GHS-OM) before individuals can be approved for work in any BSL-3 facilities. The BAC or BSL-3 Program Team will notify GHS-OM of individuals eligible to participate in the medical screening and surveillance program.

6.5.1.2 The BSL-3 medical surveillance program is risk-based and may include pre-placement medical examination, vaccination, serologic testing, medical screening, periodic medical evaluation or evaluation of occupational exposures, illnesses and injuries.

6.5.1.3 GHS-OM may require authorized individuals to undergo periodic medical evaluation or follow-up surveillance in order to continue working in a BSL-3 facility. An exit review may be requested when an individual has terminated his/her activities at BSL-3. GHS-OM will contact individuals directly.

6.5.1.4 Persons at increased risk of acquiring infection or for whom infection may have unusually serious consequences will be informed of their elevated risk by GHS-OM prior to gaining access to the laboratory. If additional protective measures will be required, they will be evaluated by the BAC and/or IBC after communication with GHS-OM.

6.5.2 Exposure Response

6.5.2.1 An individual who has a potential exposure or who experiences any unusual or unexplained symptoms during or following a period when they have been working in a BSL-3 facility will notify GHS Occupational Medicine as soon as possible, but no later than 24 hours, and complete an Injury/Illness/Exposure report (https://cfp-isca.cit.cornell.edu/accinj/) within 48 hours. If medical evaluation and care are obtained elsewhere, the individual will contact GHS-OM as soon as possible and complete an Injury/Illness/exposure report. GHS-OM will contact the BSO via email or phone call.
6.5.2.2 Individuals will report potential exposure incidents and suspected breaches of containment to his/her supervisor and a member of the BSL-3 Program Team as soon as possible, but no later than 24 hours after an incident. The BSO will contact GHS-OM via email or phone call. GHS-OM will initiate appropriate medical follow-up measures to any incident or potential exposure.

6.5.2.3 Post-exposure monitoring measures, if required, will depend on the type of exposure, the type of biohazardous material or infectious agent, the various incubation periods of the infectious agents, and the health status of the exposed individual, as determined by GHS-OM.

6.5.2.4 The BSO will report incidents of potential exposures or breaches of containment to the IBC, IACUC and CARE (if ABSL-3), GHS-OM, EHS Director, Office of the Vice Provost of Research and ORIA within 8 hours of being notified.

6.5.2.5 All investigations of exposures or breaches will be formally conducted by a minimum of two EHS staff members. Upon completion of the investigation an initial report will be made available within 48 hours to at least the EHS director, ORIA, and PI.

6.5.2.6 The BSL-3 Program Team will investigate failures of a building system or other control measure (e.g., engineering, SOP) that resulted in a potential exposure. Access to the laboratory may be restricted until the BSL-3 Program Team has completed their investigation and determined that it is acceptable to resume work in the facility.

6.5.2.7 The Institutional Official in the Office of the Vice Provost of Research is required to notify the appropriate state and federal authorities in writing of a regulated reportable incident (e.g., release of a genetically modified organism, exposure to infectious agents, and any incident involving a select agent).

6.5.2.8 Specific exposure response procedures will be described in the SOPs for each BSL-3 facility or project.

7.0 References

Biosafety in Microbiological and Biomedical Laboratories 5th edition
WHO Laboratory Biosafety Manual 3rd Edition
Laboratory Biosafety Guidelines – Canada 3rd Edition
Guidelines for Research Involving Recombinant DNA Molecules-NIH (rev. May, 2011)
Appendix A-5-3-2012

Over View of BSL3 Workflow

Start

If application includes animal work

PI submits IACUC protocol or amendment

PI submits BSL3 Application or Amendment and SOP’s to IBC

BAC Review

PI to work with BSL3 program team to ID access requirements (and CARE req. if ABSL-3)

BAC needs additional information

Yes

PI notified of approvals and conditions by IBC and IACUC

No

BCAC obtains IACUC via eSirius if animal use is indicated

IACUC Review

Approved?

Yes

Yes

PI notified of approvals and conditions by IBC and IACUC

No

All personnel have completed access requirements*

Space Access granted. Work can begin.

* = Training, Demonstration of Proficiency, Medical Screening and Surveillance and Respiratory Protection Program

Black = Principal Investigator (PI)
Green = Biosafety Level 3 Advisory Committee (BAC)
Purple = Institutional Biosafety Committee (IBC)
Blue = Institutional Animal Care and Use Committee (IACUC)
Red = Biosafety Level 3 (BSL3) Program Team

Approved by: Institutional Biosafety Committee
Last revised by: Dennis J. Shaw
Revision date: 4/10/2012