Elements of a Biosafety Program

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Elements of a Biosafety Program

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Introduction

Biosafety as a professional discipline has expanded dramatically during the 1990's as a result of increased numbers of regulations and guidelines directed toward reducing the potential for occupational illness and adverse environmental impacts from microorganisms and biological materials from many sources.

Biosafety deals with safe methods for managing infectious materials in the laboratory. This is accomplished by protection of personnel and the immediate laboratory environment from exposure to infectious agents (primary containment) and protection of the environment external to the laboratory from exposure to infectious materials (secondary containment). Primary containment includes good microbiological practices and techniques as well as safety equipment such as biological safety cabinets. Secondary containment includes good operational practices and facility design practices. Biosafety to some individuals also deals with the preparation of safe, US Food and Drug Administration (FDA)-regulated biologicals that are free from microbial contamination (biological safety).

The tools of the microbiologist are now used by more researchers with diverse areas of expertise use the tools of the microbiologist to conduct research in molecular biology and genetics. Therefore, the need for microbiological procedure and containment practice training and education for a wide audience has increased at a time when fewer individuals specialize in microbiology. Biosafety officers need a good foundation in microbiological practices in order to assist staff members who may be encountering microorganisms for the first time.

This chapter describes the major elements of the biosafety program at Johns Hopkins University and Johns Hopkins Hospital with comparisons to programs in other settings. For

information about chemical safety, life safety, occupational safety, and radiation safety programs, the reader should consult publications specifically directed to those disciplines. The information in this chapter is presented in a structured format to assist individuals who are organizing a biosafety program.

Institutional Responsibility

The employer is ultimately responsible for promulgating and enforcing safety policies and programs. Therefore, the senior administration must designate one or more persons who will carry out the institution's safety programs. The individual who heads up the overall safety program should be at the director level of the organization and have a staff who will carry out the daily activities required by the safety program. The principal investigator, chief, laboratory supervisor, or section head has the day-to-day responsibility for ensuring that employees receive proper safety training and follow the institution's safety policies.

Biosafety Administrative Reporting

The administrative reporting structure for biosafety programs varies with the size of an organization and the service or product it produces. Generally, a biosafety program is one of several employee safety and health programs, which may include chemical safety (industrial hygiene), radiation safety, life safety, and occupational safety (workers compensation). Depending on the size and diversity of an organization, there may be several other employee-related safety and health programs such as employee health, medical surveillance, and employee staff and family assistance programs.

The biosafety profession has recently become a prominent specialty because of the breadth and depth of biosafety-related guidelines and regulations that have been enacted by the government to protect the health and welfare of the public. Biosafety officers need to pass on this information to employees and students.

There are now biosafety registration and certification programs for microbiologists who choose to make this field their profession. The American Biological Safety Association (ABSA) has two programs that recognize biosafety professionals. The ABSA Registered Biological Safety Professional (RBP) program recognizes individuals with appropriate microbiological training and biosafety experience. The ABSA Certified Biological Safety Professional (CBSP) program recognizes individuals with microbiological training and biosafety experience who have passed the American Academy of Microbiology Specialist Microbiologist examination in Biological Safety Microbiology.

Academia

Academia includes many types of organizations, from small colleges, undergraduate universities, large undergraduate and graduate universities, and universities that include a medical school and a teaching hospital.

Small colleges and some undergraduate universities may have one individual who carries out the functions of a biosafety officer, industrial hygienist, radiation safety officer, and occupational safety officer. This individual may report to a department chair, director of human resources, director of security, director of risk management, administrative dean, or academic dean.

Universities often have a diversified safety program with at least one safety officer and a radiation safety officer. The biosafety program may be a component of the safety officer's duties or biosafety responsibilities may be assigned to a faculty member with an appropriate background in microbiology. There may be a safety manager or safety director to whom the safety officers report. This individual often reports to a director of risk management, director of human resources, or an administrative or academic dean.

Universities with a medical school and a teaching hospital are structured in two ways. Often the medical school campus is physically separated from the rest of the university. When this occurs, there may be distinct biosafety programs with different reporting structures at the two campuses. The medical campus may have a safety program that reports to an executive medical director or an executive administrative or academic director. The other university campus may have a safety program that reports to a director of risk management, human resources, or an administrative or academic dean. These safety programs often employ individuals with expertise in each of the major safety areas, biosafety, chemical safety, radiation safety, occupational safety and life safety.

Some universities, such as Johns Hopkins University, have a medical school, a teaching hospital, a school of public health, and a school of nursing on one campus and traditional undergraduate and graduate schools of arts and sciences, continuing studies, and engineering at another campus. These universities may have a combined safety program that includes the university and the hospital. The combined safety program offers the advantage of a uniform application of safety policies and procedures at all schools and the hospital. Employees and students need to become familiar with only one set of safety policies and procedures, which makes it easier for them to move between schools and departments on the different campuses.

Employee safety training and health records of a combined safety program can follow employees when they move between different administrative units of the university and hospital.

The reporting structure for a combined university and hospital safety program consists of managers of each safety section; Biosafety, Chemical safety, Life safety, Occupational safety, and Radiation safety, reporting to an executive director of safety and health. This director may chair a joint committee on health, safety and environment composed of directors of major functional units at the hospital and university. This executive director may report to an academic executive of the university and an executive head of medical affairs at the hospital.

The combined safety and health organization at Johns Hopkins has both hospital and university employees. The safety program includes; Biosafety, Chemical safety, Life safety, Occupational safety, and Radiation safety. The employee health program includes; Occupational health services (employee health clinic), Occupational injury (workers compensation clinic and office), Staff and family assistance programs, and a Center for Occupational and Environmental Health. The Center provides safety services and occupational medicine services to companies and organizations nationwide.

This combined safety and health organization is named Johns Hopkins Institutions to reflect the fact that it combines both the for-profit hospital and the non-profit university safety and health programs.

Government

Government safety programs often resemble a university structure with a chief or director of safety and health with direct reports who manage biosafety, chemical safety, life safety, and radiation safety. A safety representative in charge of biosafety may report to a supervising

division chief in charge of safety personnel who reports to a division chief responsible for the overall safety training and procedures of the facility.

Supervisors ensure that employees receive appropriate biosafety training. The safety office responds to emergencies and publishes biosafety regulations and procedures for personnel and facility operations. In military laboratories, a chief or director of safety and health may report to the chief of the medical division, who reports to the commander of the facility.

The management structure of government safety and health programs has a more defined chain of command than is the case at most universities. The safety staff may report to a supervisor who passes the information up the chain of command to the individual who is authorized to make decisions.

Industry

Industry safety reporting structures depend on the size of the organization. Small companies may have a safety consultant that covers all aspects of safety programs and reports to the president of the company. Larger companies may have a safety officer on staff who covers all aspects of safety. This safety officer may report to the company president, operations director, risk management director, human resources director, or other director. Biosafety issues are incorporated into the duties of this position.

Large companies often have a larger safety staff with section managers of each safety discipline (biosafety, chemical safety, life safety, occupational safety, and radiation safety). The reporting structure varies depending on the company's product or service.

Most companies have a life safety and chemical safety officer who reports to a director of medical affairs, quality assurance, operations, human resources, risk management, or executive

administration. Companies with several facilities worldwide may have a safety staff headquartered at the home office with general safety staff members located at strategic plants. These individuals often report to a safety director at the home office and to a director level executive at the local facility.

Pharmaceutical and biotechnology companies have, in addition, a biosafety officer to oversee recombinant DNA, bloodborne pathogens, select agents, and other biosafety-related programs. A general safety officer, an industrial hygienist, or a research scientist may take on the duties of a biosafety officer, although many companies now employ biosafety officers who have training and experience with microbiological practices and procedures.

Biosafety Line Management Functions

The biosafety program at Johns Hopkins Institutions has both line management and advisory functions. Line management operations include those for which the biosafety program has direct responsibility. Line management can be defined as vested with a certain amount of discretion and independent judgement, or that an employee so designated is invested with the general conduct and control of his employer's business (Black, 1979).

Advisory functions are of a consulting nature to various functional units of the hospital and university. Four biosafety staff members report to the biosafety officer who reports to an executive director of employee health and safety divisions described in the academia administrative reporting section above. Specific biosafety line management activities are described in this section.

Biological Safety Cabinet Certification

The biosafety staff certify and service all high efficiency particulate air (HEPA) filter-containing equipment at Johns Hopkins Institutions. As of October 1999, this equipment consisted of:

- 788 biological safety cabinets (BSCs)
- 112 clean air benches (CABs)
- 80 positive air pressure HEPA respirators (PAPRs)
- 28 portable HEPA filter units
- 26 HEPA filter bag-in bag-out roof top units.

The supervisor in charge of field activities is certified as a National Sanitation Foundation Biological Safety Cabinet Field Certifier (**NSF 1999**). The certifier and assistant certifier receive a printout of requests for service each day from a Microsoft Access 97 database (Appendix A) that lists the service needed, the serial number and model of the equipment, the location of the equipment, and the name and telephone number of the equipment's contact person. Contact individuals are called and an appointment is made to service the equipment. Routine service, such as routine annual certifications and filter replacements, are accomplished within two weeks.

PAPRs are permanently located at appropriate clinical nursing units and biosafety level 3 (BSL-3) laboratories where they are kept plugged into battery chargers. They are checked monthly for damage and proper airflow. New PAPRs and those that require service are checked for HEPA filter leaks using a small quantity of polydisperse dioctylphthalate (DOP) particles at 10+ μg per liter at 20 psi and a photometer. Some newly purchased PAPRs may have leaks around the HEPA filter gasket, so they are leak tested before they are put into service. PAPR

filters and rechargeable batteries are routinely replaced every two to three years. PAPR service procedures are performed in a BSC.

Portable HEPA units are permanently located at intensive care nursing units, tuberculosis airborne isolation nursing units, some outpatient clinics, the emergency department, and some clinical nursing units that care for patients with low white blood cell counts. The prefilters in these units are changed every three months to extend the life of the HEPA filters. Airflow is checked with a hot wire anemometer when the prefilters are changed. The HEPA filters are changed every three years after the units are decontaminated with formaldehyde gas.

Biosafety division staff deliver portable HEPA units and PAPRs to hospital locations that do not have permanently stationed equipment. This ensures that the hospital staff receive training on the proper use of the equipment and makes it easier for the biosafety staff to track equipment locations.

Emergency Response

The biosafety division provides on call emergency pager service coordinated from a central telephone switchboard that covers the hospital and university medical campus and from the security switchboard at the undergraduate/graduate university campus. Emergency service consists of moving portable HEPA filter units or PAPRs to hospital inpatient areas that require supplemental air exchange or staff member respiratory protection, such as tuberculosis airborne isolation rooms. Emergency BSC and CAB requests including service of inoperable equipment and replacement of fluorescent lamps and ultraviolet lamps are handled within one day. Other emergency responses often involve biological spills that may be handled by telephone or by an on-site visit.

Environmental services (housekeeping) departments are trained to handle biological spills including blood spills and fluids leaking from bags. Facilities departments are trained to wet vacuum large spills from defrosting freezers and sanitary sewer overflows into a fifty-five-gallon tank containing diluted bleach.

IBC Registrations

The chair of the Institutional Biosafety Committee (IBC) is a professor level faculty member. The IBC membership consists of employees and two non-employee members as described by the National Institutes of Health (NIH) Recombinant DNA Guidelines (**R-DNA Guidelines 1999**). The IBC reports through the biosafety officer to the Joint Committee on Health, Safety and Environment. The biosafety division is responsible for maintaining an Access 97 database of research registrations for the IBC. The NIH IBC began to register research with pathogens in 1988. In 1989 the biosafety division at Johns Hopkins expanded the recombinant DNA registration program, started in 1975, to include research with pathogens, sheep and goats (potential transmission of Q fever), and non-human primates (potential transmission of Cercopithecine herpesvirus 1 or B virus). Research with human tissue (blood, internal body fluids, unfixed tissue, and human tissue culture) was added in 1991 to comply with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (**OSHA 1991**). Research with select agents (**CDC 1996**) was added to the IBC database program in 1998. As of October 1999, there were 986 registered, active research projects including over 53 genera of pathogens.

The IBC database is indexed by the name of each principal investigator and registration paperwork is kept in principal investigator files. The registrations are project specific, not

laboratory specific. A university information checklist (Appendix B) accompanies each grant application submitted to the research administration for approval. The checklist contains a biosafety section that is completed by the principal investigator. This section is divided into specific categories that the principal investigator checks off and fills in his or her project-specific registration number. The registration number is obtained from the biosafety division for research with:

- Pathogens
- Recombinant DNA
- Sheep and goats
- Non-human primates
- Select agents
- Human tissue.

In addition to an IBC registration number, each principal investigator must fill in the IBC approval date for non-exempt recombinant DNA projects, select agent projects, and projects conducted at laboratory BSL-3 and animal BSL-3.

Most of the select agent-related research projects at Johns Hopkins involve toxins used in tissue culture by neurologists and cell biologists. The quantities involved in this research are small and most of the toxins, except botulinum toxin, have an LD_{50} greater than 100 ng per kilogram animal weight and are therefore exempt from the regulation.

All investigator submissions that have checked off biosafety related sections on the university information checklist are sent to the biosafety officer for review. This ensures that the research has received appropriate approval by the IBC and registration by the biosafety division. The biosafety officer also reviews animal research. The Institutional Animal Care and Use

Committee sends copies of the animal research protocols to ensure that the research has received appropriate review for biosafety related practices and procedures. The Institutional Review Boards (human subjects committees) also send copies of research protocols that involve human subjects research with pathogens, recombinant DNA, or human tissue.

The IBC research registration programs have received acceptance by principal investigators and departmental administrators because the turnaround time for registration of most applications is within 24 hours and the forms are easy to fill out (Appendix C1-C5). The forms are available at the Johns Hopkins intranet web site or by fax from the biosafety division secretary. Department administrators are familiar with this process and help principal investigators register their research before the proposals are sent to the research administration for signature.

The biosafety division updates each research registration on its annual anniversary date of initial registration by sending a letter, including details of the previous registration, to each principal investigator (Appendix D1-D2). The investigator makes changes on the update letter, usually changes in personnel, and returns it to the biosafety division so that the database can be updated. A confirming letter with a revised registration number is then returned to each principal investigator (Appendix E1-E2). If there are significant changes in a research project, a new research registration form is sent to the principal investigator.

Incident Reviews

The biosafety division collaborates with the occupational injury clinic, occupational health clinic, and infection control staff to investigate occupational exposure incidents involving biological materials. The investigations are conducted to determine whether changes in

administrative, engineering, or personal protective equipment policies and procedures can be implemented to reduce the probability of subsequent occupational exposure incidents. The incidents usually involve:

- Spills of biological materials
- Exposures involving potential bloodborne pathogens
- Improper use of personal protective equipment
- Primary or secondary biological containment issues such as defective autoclaves, centrifuges, biosafety cabinets, and laboratory ventilation.

Workplace Complaints

Workplace employee complaints include objections to musty smells and perceived allergic reactions to fungi in the work environment. The industrial hygiene division is the first responder to indoor air quality (IAQ) issues. When appropriate, the biosafety division conducts airborne microbial surveys with a portable, centrifugal air sampler using rose bengal agar for fungi and trypticase soy agar for bacteria. Results from over four hundred microbial surveys show that indoor microbial counts are considerably lower, usually ten-fold, than the accompanying outdoor control samples that are always taken at approximately the same time and building location as the indoor samples.

Only two IAQ microbial surveys had significant numbers, greater than 500 colony-forming units per cubic meter (**ACGIH 1989**), of fungi or bacteria, during the past eleven years. One IAQ area involved overcrowding of a small office area where significant numbers of normal bacterial skin flora were isolated. The other IAQ area involved a chronically wet basement area

that was colonized with environmental fungi that were dispersed in significant numbers throughout the building.

Record Keeping and Information Management

The health and safety information management system was expanded in 1991 to enable routine backups and to connect employee safety training records to the hospital and university payroll mainframe computers (Appendix F). As of September 1999, there were 102,759 recorded training records. Employee social security numbers are used to index the records. This system was further expanded in 1993 to include employee occupational health records (not shown in Appendix F). The connection to payroll computers is an important aspect of the safety information system because payroll systems are the most reliable source of employee information such as job title, office location, department, and office telephone number.

Employee position changes between functional units and between the hospital and university payroll systems are captured by the safety information database. Employee information on the payroll systems not needed by health and safety programs, such as employee pay and human resources confidential personnel records, is hidden before it is uploaded from the mainframes to the health and safety database.

The health and safety server uses an Access 97 database available as a read only file to health and safety functional units. The employee medical records are only available to the occupational health and occupational injury divisions of the health and safety department. Employee records are maintained on the database for thirty years after individuals terminate their employment.

HEPA Equipment Databases

The biosafety division database for BSCs, CABs, and bag-in bag-out filter systems was started in January 1989, as was the research database. The biosafety division database software migrated from DB-2, DB-3, DB-4, and Access 95 to Access 97 software (Appendix G). The data fields for each piece of equipment contain specific information about the equipment owner, the contact person for payment, and the person in the laboratory to contact to arrange for service. The equipment is indexed by serial number and contains certification and service details with dates, and other information such as the presence of a thimble connection to the building exhaust and the blower speed percent of maximum (an indicator of remaining filter life).

An assistant biosafety officer manages the database and sends out letters to contact individuals one month before their BSCs and CABs need to be certified (Appendix H). All equipment is certified annually, except pharmacy and biosafety level three (BSL-3) laboratory HEPA equipment. This equipment is certified every six months. The letters request payment to the biosafety division before the equipment is certified.

The annual certification charge is approximately half the cost of an outside certifying company and includes free parts and labor, except for replacement filters and ultraviolet lamps. The in-house program saves approximately one hundred thousand dollars per year in certification and service costs.

The portable HEPA unit database (Appendix I) and the PAPR database (Appendix J) were started in 1994 to track each unit by serial number. Certification information, filter changes, other service procedures, location of the equipment, and contact person at the equipment location, are maintained on the databases by the biosafety division staff. Emergency

deliveries are recorded so that arrangements can be made to permanently place equipment at hospital areas that request many emergency deliveries.

The bag-in bag-out database (Appendix K) includes magnehelic gauge readings obtained by the biosafety staff every three months. There are often three gauges on each bag-in bag-out housing. One gauge measures the pressure drop across the pre-filter(s), another reads pressure drop across the HEPA filter(s) and a third gauge measures the drop across the pre- and HEPA filters. These gauge readings are used to predict when pre-filters and HEPA filters will need changing. This information is sent to each facilities department so they can budget for the anticipated filter changes.

Research Databases

Biosafety-related research registered with the IBC, as described above, is maintained on an Access 97 database that is indexed by a unique research registration number for each project and ordered by principal investigator name (Appendix L). The letter prefix for each research IBC registration number is either ‘A’, ‘B’, or ‘D’, followed by the initial date of registration (YYMMDD), the sequence number for project registration for that day (starting at 01 to 99), and the registration year (for example, 01 for first year, 10 for tenth year). The letter prefix indicates whether the project is; ‘A’ - Moderate to high risk biohazard project (often BSL-3), ‘B’ - Low to moderate risk biohazard project (BSL-2), or ‘D’ - Recombinant DNA project.

The registration number does not imply that the Johns Hopkins Institutional Biosafety Committee (IBC) has reviewed and approved the research project. Most potential pathogenic agent or material projects with letter ‘B’ prefixes and many recombinant DNA projects do not require IBC review (they are given a registration number only). Examples of projects that may

require IBC approval are: Gene therapy of human subjects; Recombinant DNA with pathogenic host/vector gene delivery systems; Recombinant DNA research with intact animals; and Biosafety Level 3 research projects.

If there is a date in the 'IBCAPROV' column, the IBC has reviewed and approved the project on the designated date. Recombinant DNA projects that do not require IBC review are marked 'NA' (not applicable).

There is a separate select agent research database (Appendix M). This database is separate from the main IBC research database because there are many data fields that are specific to the select agent registration program. The details of the type of select agent, method of destruction, storage location, etc. are recorded for each research project using select agents.

Training Databases

Biosafety training records on Access 97, indexed by social security number for each employee, are coded by a three-digit number that is specific to each training program (Appendix F). Biosafety training programs include:

- BSL-3 laboratory training
- Bloodborne pathogens training
- Infection control training
- Risk management training for physicians
- Certification for packaging and shipping of infectious substances and diagnostic specimens (Appendix N)
- Biological safety cabinet operating procedures
- Tuberculosis control training

- Positive air pressure HEPA respirator training.

The training database also includes training programs such as:

- General orientation
- Graduate student training
- Hazard communication training
- Respirator training and fit testing
- Noise control training
- Asbestos awareness
- Molecular Resonance Imaging safety
- Tow motor training
- Radiation safety
- Chemical laboratory safety
- Mercury spill training
- Hazardous chemical spill training
- Formaldehyde protection
- Ethylene oxide exposure procedures
- Ergonomics
- Fire safety.

Sharing Data with Functional Units

Employee safety training compliance information is sent to functional unit directors and supervisors at the hospital and university. Each employee record in the health and safety information system was recently expanded to include the name and address or their supervisor.

Institutional policies require employees to attend mandatory training sessions and their supervisors must record employee safety compliance on the employee's annual performance evaluation form.

A letter is also sent to each employee, with a copy to their supervisor, when it is time for them to participate in update training sessions. Employee bloodborne pathogens training and positive pressure HEPA respirator training are repeated each year. Risk management training and certification for packaging and shipping are repeated every two years.

Risk management training information is shared with the hospital medical board that credentials physicians to practice medicine at the hospital. Physicians must complete a one hour risk management session, that includes safety training, every two years in order to maintain hospital privileges.

Active research project IBC registration printouts are sorted by principal investigator and sent to academic research administration offices at the schools of arts and sciences, medicine, and public health every few months. This information is also sent to the Institutional Animal Care and Use Committees and the Institutional Review Boards, so they can determine whether projects that come before their committees have been registered with the biosafety division.

BSC and CAB certification information, sorted by administrative department, is sent to department managers so they can arrange to have equipment in their department certified at the same time. This saves paperwork time expended by the biosafety supervisor and laboratory staff because there is one invoice to certify all of the department’s equipment instead of a separate invoice for each piece of equipment. This departmental billing system is currently in place for

the departments (oncology, pharmacy, and pathology) with the largest number of BSCs and CABs. The program is being expanded to other departments.

The occupational health services division uses the health and safety database to send reminder letters to employees and their supervisors when employees must complete their immunizations, annual tuberculin tests, or other health related activities.

Quarterly and Annual Reports

All divisions of the health and safety department at Johns Hopkins Institutions submit quarterly reports to the Joint Committee on Health, Safety, and Environment. These reports, along with annual summary reports, document the activities of each health and safety division.

The biosafety division reports include information about:

- Outside agency inspections
- Incident investigations
- Construction plan reviews
- Laboratory surveys
- Training sessions
- Communication activities
- Details of new research registrations
- Purchases of new HEPA filter equipment
- Movement of existing HEPA filter equipment
- Service activities for BSCs, CABs, bag-in bag-out HEPA systems, portable HEPA filter units, and PAPRs.

Tables and graphs are used extensively in these reports so that activities during the previous four quarters and prior year information can be compared to activities documented in the current report.

Other health and safety divisions report on other biosafety-related activities. For example, the occupational injury clinic reports all occupational exposures to bloodborne pathogens. These reports include the functional unit, type of exposure, what the employee was doing when the exposure occurred, the source patient's serological status if known, and whether the employee started and completed a twenty-eight-day course of post exposure prophylaxis.

Biosafety Program Review and Revision

The quarterly and annual reports are used to analyze the daily activities of the biosafety division so that areas of responsibility that need more resources can be identified. This may involve the purchase of more equipment such as portable HEPA filter units and PAPRs, or adding more biosafety division personnel to manage databases, training records, and service functions.

Biosafety Advisory Functions

The biosafety division provides technical advice to several functional units at the hospital and university. These advisory functions are presented in the form of documented recommendations or telephone conversations. All incoming telephone calls are logged in by time, subject of the call, and ending time. The telephone logs are filed by month and stored for several years.

Construction and Renovation

Construction and renovation plans are forwarded to the health and safety department and logged in by date of receipt. The plans are circulated to the biosafety, chemical safety, life safety, and radiation safety divisions for review and comment.

Recommendations are combined into a letter and sent to the appropriate design and construction department. Biosafety division reviews concentrate on BSC placement within laboratories, BSC thimble connections, directional negative airflow volumes of 50 to 100 cubic feet per minute (cfm) into laboratories, locations of laboratory supply and exhaust outlets, and BSL-3 laboratory design and construction methods (Appendix O).

Communications

Several methods of communication are used to transmit information to hospital and university faculty and staff because no single method will reach everyone.

Brochures and pamphlets

Biosafety brochures and pamphlets are handed out at new employee orientation sessions and at training sessions for current employees. There are multiple page brochures for the bloodborne pathogens control program and the tuberculosis control programs. A brochure is handed out at bloodborne pathogen training sessions. It contains a graphic illustration of the twenty-four hour bloodborne pathogen exposure hotline, suitable for posting, and describes the details of the hepatitis B virus vaccine program, the post exposure prophylaxis program, and the confidential medical evaluation program for employees and students who have occupational exposures to bloodborne pathogens.

A trifold brochure containing fire, security, medical and exposure hotline numbers, and details of the responsibilities of each health and safety division is handed out at most training and orientation sessions. This brochure is also used to document risk management training for hospital physicians and new house staff. A tear-off panel of the brochure is filled out and handed in at the end of the training session. This information is entered in the training database.

Email broadcasts

Email broadcasts are used to send biosafety training schedules and important biosafety information to all employees and students on the combined hospital and university email network. Recent broadcasts detailed changes in dates for packaging and shipping certification training and communicated the enhanced enforcement of shipping regulations by the Federal Aviation Administration Division of the Department of Transportation.

Online intranet web site

The biosafety division established an intranet safety and health department web site accessible to individuals on the internal network. The safety web site contains:

- The university safety policy and procedure manual
- The biosafety manual
- The current NIH Recombinant DNA Guidelines (**R-DNA Guidelines 1999**)
- The current CDC/NIH Biosafety Guidelines for Biomedical and Laboratories (**CDC 1999**)
- The CDC Select Agents Registration program (**CDC 1996**)

- All research registration forms that can be downloaded, filled out, and sent to the biosafety division.

Policy Manuals

New editions of the Johns Hopkins Institutions Safety Policy and Procedure Manual and the Biosafety Manual were published in 1994. They were published as soft cover bound manuals with three-hole punched spines. The manuals have pages with serrations in the left margin so that the manuals will lay flat for photocopying. There is no plan to revise and reprint these manuals because they are now available with hyperlinked indexes on the intranet web site.

Signage

Laboratory signage has been uniform throughout the hospital and university since the late 1970's. The signage was revised in 1994 to permit up to eight stickers per nine by nine-inch yellow placard. The placards are mounted with double-sided tape to the wall next to laboratory doors where people entering the room will notice them. The placards contain emergency contact information for the safety department and the office and home telephone numbers of the laboratory director and supervisor.

Clear, two- and one-half inch high by two inch wide stickers with black, red, yellow, or orange graphics, are placed on the yellow placards so that the yellow shows through the stickers. The selection of stickers includes:

- Biohazard symbol
- BSL-2
- BSL-3

- BSL-3 work practices
- Infectious agents
- Potentially infectious agents
- Infected animals
- No food or drink
- Eye protection required
- Radioactive materials
- Radiation area
- High radiation area
- Microwave radiation
- Ultraviolet light
- Laser radiation
- Cancer suspect agent
- Cancer hazard
- Chemical storage area
- Corrosive materials
- Toxic chemicals
- Toxic gas
- High voltage
- Electrical hazard
- Flammable materials
- Hearing protection required
- Protective clothing required.

The yellow placards for BSL-2 laboratories have bold letters at the top stating “Caution - Admittance to Authorized Personnel Only”. Placards for BSL-3 laboratories state “Caution - Restricted Area – Admittance to Authorized Personnel Only”. The entrances to BSL-3 laboratory anterooms are locked. They can be opened with either a special key or an authorized employee's ID card. Housekeeping, facilities, and other staff have been trained to understand the difference between these two placards. They may enter BSL-2 areas, but they must have authorization from the laboratory staff before they enter a BSL-3 area.

Weekly Publications

The health and safety department places training announcements and policies in two weekly publications. The ten-page university newspaper permits the full text of policies and procedures to be published. The one-page, legal size, double sided, hospital newsletter is used to publish short announcements. The heath and safety department pays for a special edition of the hospital newsletter when new policy announcements, such as the bloodborne pathogens control program and the tuberculosis control program are started. These publications reach the greatest number of employees and students.

Training

Biosafety-related training is presented by biosafety division staff and occupational health staff to hospital and university employees and students. The details of the presentations are documented and kept on file for inspection by outside agencies, such as the state occupational health and safety administration. Attendance at all training sessions is recorded on

sign in sheets that include the trainee name, social security number, and department. All training information is entered into the training database.

New employee safety orientation is presented by a general safety officer using a computer presentation program that includes fire, hazard communication, bloodborne pathogens, and emergency contact information.

Biological Safety Cabinets

When invited by laboratory groups, biosafety division staff present a training program on the proper use of BSCs which includes a twenty-minute video from the Eagleson Institute (**Eagleson 1991**). Topics covered include the design, operation, and certification of BSCs, using gowns with knitted cuffs and gloves, disinfection of work surfaces with an iodophore disinfectant, placement of materials on the work surface, and the effects of drafts and foot traffic on the air curtain at the front of the BSC. Use of CABs is discouraged.

Bloodborne Pathogens

Bloodborne pathogens training is presented by the biosafety staff, occupational health services, and the nursing department (self-study). OSHA required information is presented along an expanded discussion of the exposure hotline, the HBV vaccination program, glove materials, waste disposal, and retractable syringes.

Other Pathogens

The biosafety division staff present expanded training to staff and students who will work in BSL-3 laboratories. The BSL-3 laboratory's standard operating procedure manual is

reviewed. The proper use and removal of personal protective equipment, autoclave decontamination of laboratory waste, and general housekeeping procedures are discussed. The training also includes specific information about the pathogens being researched and the availability of medical surveillance by occupational health services.

DOT and ICAO Dangerous Goods

The biosafety division staff present a two to three hour, hands on training session that covers all aspects of packaging and shipping infectious substances, diagnostic specimens, biological products, dry ice, liquid nitrogen, and dangerous goods chemicals often shipped by biomedical research laboratories.

The training is based on the current edition of the trade association manual published by the International Air Transport Association (**IATA 1999**) that incorporates the International Civil Air Transportation Organization (**ICAO 1998**) regulations. The revision of the U.S. Department of Transportation (DOT) regulations for shipment of infectious substances and diagnostic specimens (**RSPA 1998**) is also reviewed.

The training sessions incorporate pre- and post-tests to document the training and to enhance the learning experience. Examples of approved and non-approved shipping containers are circulated to the audience. The training sessions are presented every two months.

Individuals who took the course two years ago are sent letters to remind them to attend a new training session. This complies with the ICAO requirement that shippers receive training every two years.

Respiratory Protection

The biosafety division staff present respiratory protection training for the use of PAPRs, that are loose fitting, positive air pressure HEPA respirators and are therefore exempt from the full OSHA respiratory protection fit testing program (**OSHA 1998**) administered by the industrial hygiene division.

Employees are asked to fill out a short version of the OSHA medical surveillance questionnaire. The questionnaire is forwarded to occupational health services for review. Employees are given a copy of the policy on the care and operation of the equipment. The functional units purchase the hoods (head covers) from hospital central supply and employees keep their personal hood in a plastic bag near their work area. The hoods are only discarded when they are damaged or become grossly contaminated.

Signage

Interpretation of signage is incorporated into orientation, bloodborne pathogen control, tuberculosis control, and BSL-3 laboratory training. A full description is also published in the biosafety manual.

Waste Decontamination and Disposal

The biosafety division staff present waste disposal training to functional units and laboratories that have difficulty following the laboratory waste decontamination and disposal policy. This training emphasizes that good microbiological practice involves autoclave decontamination of microbial cultures for at least one hour.

The training also includes a discussion of the state of Maryland statute that prevents landfilling waste materials that may be perceived as contaminated hospital or laboratory waste.

The policy requires that autoclaved microbial cultures, laboratory waste, and hospital waste from clinical areas be incinerated in a regional medical waste incinerator. Trainees are reminded that the statute is based on the public's perception of hazard associated with this waste, not necessarily on the actual risk of disease transmission.

Policies

Johns Hopkins Hospital and University implemented biosafety policies in the 1970's. The earliest policies followed the National Cancer Institute laboratory practice guidelines (**NCI 1974**) and the NIH recombinant DNA guidelines (**R-DNA Guidelines 1999**). Many other policies have been developed over the past twenty years.

Draft policies are submitted to the Joint Committee on Health, Safety and Environment for approval before they are published. Approved policies are sent to all administrative units and placed in weekly newsletters.

Good Laboratory Practices (BMBL)

Current biosafety laboratory policies generally follow the CDC/NIH guidelines for research in biological and biomedical research laboratories (**CDC 1999**), but in some cases the university policies are more restrictive (Appendix H). The recommendation for BSL-3 laboratories is a bag-in bag-out HEPA filtration system for BSL-3 laboratory exhaust. Cultures of microorganisms must be decontaminated by autoclave. Autoclaved liquid waste is discarded into the sanitary sewer system. Autoclaved solid waste is discarded into a red bag-lined biohazard box. BSL-3 laboratory design policy recommends a double-sided autoclave with a bioseal between the BSL-3 laboratory and the adjacent area on the other side of the wall.

Policy recommends that all laboratories have Class II, Type B3 BSCs thimble connected to the building exhaust system. BSL-3 laboratories must have one hundred percent shutoff dampers between BSC thimble connection and the laboratory exhaust system. BSL-3 laboratories also have an alarm system in the laboratory to warn of laboratory exhaust flow failure and an automatic supply air shut off when this occurs. The biosafety division recommends that seamless integral cove flooring be installed before BSCs and other permanent equipment are placed in the room. There are no vertical pipe floor penetrations and card access to the anteroom is installed for security.

Standard Operating Procedures

All BSL-3 laboratories have a standard operating procedure (SOP) manual. An electronic template manual is given to each principal investigator to complete with specific procedures for that laboratory. The draft SOP is reviewed by the biosafety staff, the IBC, and approved by the Joint Committee on Health, Safety and Environment. A typical SOP index is included (Appendix P). The original copy is signed by the biosafety officer, the chair of the joint safety and health committee, the chair of the IBC, and the director of the animal services division, if appropriate. The biosafety division keeps the original, signed copy in the principal investigator's personnel file and a copy is sent to the principal investigator.

Good Manufacturing Practices (cGMP)

The Food and Drug Administration (FDA) current Good Manufacturing Procedures (**FDA 1996**) guidelines are followed for research laboratories that produce gene therapy products intended for Phase 1 and Phase 2 clinical trials. The biosafety division consults on the design

and construction of the facility with the research staff and facilities design and construction. Issues covered include BSC construction and performance specifications that include a thimble connection to the building exhaust system. The Class 10,000 clean room supply air HEPA filters are mounted in a metal ceiling and can be leak tested and serviced within the clean room. The heating, ventilation and air conditioning (HVAC) system is designed to be constant air volume with at least eight to ten air changes per hour, a recommendation followed for all biomedical research laboratories.

Laboratory Surveys

The biosafety division staff surveys twelve BSL-3 laboratories every six months and sends a report to the principal investigator and the department administration. The staff also assists with the training of general safety officers who survey hospital clinical laboratories and soiled utility rooms, as well as all university research laboratories. Each department is surveyed separately.

Biosafety staff participate in quarterly surveys conducted by the Institutional Animal Care and Use Committees. The most common deficiencies include improper laboratory signage and no hand soap or paper towels.

Biosafety-related elements of laboratory surveys include:

- Autoclave repair and operation records
- Proper use of personal protective equipment
- Appropriate laboratory clothing
- No food or drink in the laboratory
- Proper use of sharps and sharps disposal containers
- Proper use of red bag-lined biohazard boxes for disposal of laboratory waste

- Proper laboratory signage
- Current certification of BSCs and CABs
- Hydrophobic HEPA filters on laboratory vacuum outlets
- Decontamination of microbial cultures before disposal into red bag-lined biohazard boxes.

The instrument used to record the survey for each laboratory is a two-page, carbon-free checklist of key elements (Appendix Q). The safety surveyor retains the original and the copies are combined and sent to the department administration. Representatives from a department's administration and facilities accompany the safety officer on these surveys.

The most common biosafety-related deficiencies include improper laboratory waste disposal, no HEPA filters on laboratory vacuum systems, and improper handling of sharps.

Committee Attendance

Biosafety staff participation in committee meetings is a central element of the biosafety program because they are a good forum in which to communicate good biosafety practices and procedures.

Environmental Monitoring Committee

This committee focuses on chemical and industrial hygiene issues involving employee exposure to chemicals. Therefore, biosafety participation is minimal.

Institutional Biosafety Committee

The IBC is the major forum for discussion of biosafety-related issues. Committee findings are submitted to the Joint Committee on Health, Safety and Environment for approval. The committee meets when needed to approve recombinant DNA protocols, select agent registrations, BSL-3 SOP's, and to formulate policies and procedures. Telephone and fax votes are sometimes used instead of formal meetings.

Institutional Animal Care and Use Committee

Biosafety staff participate in committee surveys of animal facilities and review all animal protocols submitted to the committee. This ensures that proposed research protocols that include recombinant DNA, pathogens, sheep and goats, non-human primates, radionuclides, and toxic chemicals have has been registered with the health and safety department. Protocols that involve medical surveillance, such as annual tuberculin skin testing for employees working with non-human primates and immunization of employees working with vaccinia virus are forwarded to the occupational health services division.

Institutional Review Board (Human Subjects)

These committee deal with the human subject’s consent process and compliance with ethical standards. Although biosafety staff do not regularly attend these committee meetings, the biosafety officer reviews all IRB submissions to ensure that proposed research protocols that include pathogens, recombinant DNA, human blood, internal body fluids, and unfixed tissue are registered with the IBC. Protocol reviews often identify research that is covered by the bloodborne pathogens standard. This research is registered with the IBC as human tissue research. Personnel associated with the research involving human blood, internal body fluids,

and unfixed tissue are added to the training database so that they are notified of the bloodborne pathogen training and vaccination requirements.

Infection Control Committee

Attendance by the biosafety officer at these monthly, patient-related hospital epidemiology and infection control committee meetings is important to the biosafety program. Issues recently discussed at this committee have included:

- Placement of PAPRs and portable HEPA filter units at appropriate nursing units.
- Removal of carpeting in patient areas to reduce the number of airborne particles, including fungal spores.
- Minimization of flower beds near areas where bone marrow transplant patients enter the hospital.
- Development of a bioterrorism response plan.
- Revision of the hospital disinfection program to include dilute bleach for blood spills and a water-based quaternary ammonium disinfectant for general disinfection.
- Use of an asbestos-style containment barrier system during construction in hospital areas such as operating rooms, recovery rooms, bone marrow transplant units, orthopedic surgery units, and intensive care units.

Quality Control Committee

The hospital quality control committee includes development of policies and procedures involving administrative and engineering controls to enhance employee and patient exposures to potential pathogens. A health and safety department representative attends these committee

meetings to provide input on employee safety-related issues. Recent biosafety-related issues discussed at this committee include: Change of to a mail box style sharps container, implementation of a needleless intravenous system, change from latex to vinyl examination gloves on the nursing units, and design of decontamination procedure for a vacuum shuttle delivery system.

Risk Management Committee

Biosafety participation is on an as needed basis when committee legal issues involve containment and medical surveillance issues related to work with pathogens or bloodborne pathogens.

Marketing and Technical Support Groups

Biosafety issues in industry marketing and technical support groups involve protection of personnel from exposure to pathogens when they use equipment manufactured by the company. For example, biosafety staff may develop protocols to evaluate the capacity of products, such as flow cytometers and blood analyzers, to produce aerosols. Biosafety staff may assist in the development of procedures for the proper use of in vitro microbiological diagnostic equipment. This information is given to a research and development department to develop safe operating procedures that can be forwarded to marketing and technical support departments.

Operations, Facilities, and Engineering Groups

Biosafety division staff review design and construction plans dealing with laboratories, hospital clinics, and impatient rooms. A close working relationship with the staff of these groups

can save time and money that may be spent to correct deficiencies after construction is completed.

Recommendations from the biosafety division often involve:

- Proper location of BSCs within laboratories.
- Thimble connection design.
- Location of bag-in bag-out HEPA filter housings with magnehelic gauges connected across both pre-filters and HEPA filters.
- Constant volume laboratory air ventilation instead variable air volume systems.
- Placement of autoclaves.
- Placement of emergency eyewash and shower stations.
- BSL-3 laboratory construction details.
- Room access to HEPA filter supply systems.

Other biosafety-related issues have involved:

- Input on the design of pyrogen-free process water systems.
- HEPA filtration of carbon dioxide manifold systems.
- Heat recovery systems to transfer latent heat or cooling to incoming supply air.
- Monitoring systems for negative pressure isolation rooms.

Summary

This chapter is organized in a format that will hopefully make a biosafety manager's organizational and regulatory functions easier. The elements of the Johns Hopkins Institutions biosafety program presented here is an example of a rather large program, although selected portions of the program may be useful to individuals who are beginning a biosafety program.

Biosafety management at large institutions has become a full time job – at Johns Hopkins Institutions it is a five-person full time job. Major increases in government regulation and adherence to biomedical/pharmaceutical industry consensus standards has required more documentation. Regulations promulgated by the Environmental Protection Agency, the Occupational Safety and Health Administration, the Joint Commission on Accreditation of Hospitals, and several state and local regulatory agencies (departments of health and environment) have produced an increase in the number of on-site inspections and fines.

Much of this regulatory activity represents an expansion from the traditional chemical and radiation safety issues to biological safety in industry, government, and university clinical and basic research laboratories. There is currently a deficit of microbiologically trained biosafety professionals to handle these new regulatory activities.

Acknowledgements

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Appendix A - BSC & CAB Daily Field Service Printout

CallDate	Building	RoomNo	SerialNo	ModelNo	Service	Priority	LabContact	Comments
1/8/99	Meyer		0101011	Ultra Z	cert	routine	John	prefer Wed.
1/8/99	John		ABYZ2	AB1000	HEPA	routine	Mary	lab locked
1/10/99	Wills		BU094	UB100	decon	priority	Joe	moving
1/10/99	Meyer		2112	CA-005	cert	routine	Mike	
1/10/99	Baer		808909	TEC9	cert	routine	Jane	
1/17/99	Baer		0101011	Ultra Z	cert	routine	Jeff	2nd call
1/22/99	Wilson		09890	XXX-6	fluor light	priority	Sue	
1/22/99	Meyer		004512	AMZP2	uv light	priority	Joe	

Appendix B - Safety Section of University Information Checklist

Will project involve or require any of the following?

The Principal Investigator must personally answer questions.

Yes No

— — 1. Use of human subjects via contact and/or survey. Use of medical records and/or personal data (primary or secondary) for data analysis? — Yes — No

Has cognizant IRB (human subjects committee) approval been obtained? — Yes — No

Has protocol been submitted for review? — Yes — No

IRB # _____ Date of last approval _____

Senior P.I. on protocol: _____ If exempt specify category number _____

— — 2. Use of live, vertebrate animals? If yes, attach a copy of the vertebrate animal section for new, competing renewal and revised applications.

Senior P.I. on protocol:_____ Protocol No. _____

IACUC Approval Date:_____ If not approved, date protocol submitted: _____

— — 3. Use of organisms pathogenic to animals or humans? Has Biosafety Division approved?

— Yes IBC Number or date of approval _____ — No (Call Biosafety Division)

— — 4. Use of hazardous and highly toxic chemicals (e.g., carcinogens, mutagens, chemicals with a NIOSH IDLH level of 5 ppm or less)? Has Environmental Health Division approved?

— Yes Number or date of approval _____ — No (call Environmental Health Division)

— — 5. Use of radioactive materials? Has Radiation Safety Office approved?

— Yes Authorization number _____ — No (Call Radiation Safety Office)

— — 6. Use of recombinant DNA? Has Biosafety Division, HS&E approved?

— Yes IBC Number or date of approval _____ — No (Call Biosafety Division)

— — 7. Use of human blood, blood products, internal body fluids, unfixed tissue? Has Biosafety Division approved?

— Yes IBC Number or date of approval _____ — No (Call Biosafety Division)

— — 8. Use of Select Agents (viruses, bacteria, rickettsia, fungi, biological toxins listed in 42 CFR 72.6)? Has Biosafety Division approved?

— Yes IBC Number or date of approval _____ — No (Call Biosafety Division)

Questions about non-safety issues are not included.

Appendix C1 - IBC Research Registration Form

REGISTRATION OF RESEARCH WITH PATHOGENS,

HUMAN TISSUE, ONCOGENES, AND TOXINS

JHU IBC # _____

DATE _____

BIOSAFETY LEVEL _____

ACTION _____

DO NOT WRITE IN ABOVE SPACE

APPLICATION MUST BE TYPEWRITTEN

1. Principal Investigator _____

Academic Title _____ Social Security No. _____

2. Department _____ Division _____

3. Addresses: Office; _____ Lab; _____ Telephone # _____

4. Project Title _____

5. Name of biological agent or toxin or description of infectious material, oncogenic material, or human material: _____

Strain, Genotype, Catalog No. or CAS No: _____

6. Is agent or material a potential human or animal pathogen or toxin? Human ( ) Animal ( ) Both ( )

If a toxin, is LD_{50} more than 100 nanograms per kilogram body weight? Yes ( ) No ( ) Don't know ( )

7. Do you work with quantities greater than 1 liter? Yes ( ) Largest volume No ( )

8. Do you inactivate the agent prior to other laboratory manipulations? Yes ( ) No ( )

Inactivation Method(s) Used: Heat ( ) Chemical ( ) Radiation ( ) Other ( )

9. Do you concentrate the agent or material? Yes ( ) No ( )

Method(s): Centrifuge ( ) Filtration ( ) Precipitation ( ) Other ( )

10. Do you insert this agent or material into intact animals? Yes ( ) No ( )

If Yes, species & location of animal housing. _____

11. Biological containment level required: Biosafety Level BSL-1 ( ) BSL-2 ( ) BSL-3 ( )

12. Do you request biological monitoring or medical surveillance? Yes ( ) No ( )

13. Please list all professional personnel, employees and students involved in the project who will come into contact with these materials:

NAME	**Mailing Address**	**Social Security No.**
_____	_____	_____
_____	_____	_____
_____	_____	_____

14. Please attach a brief overview of the proposed research containing sufficient information to ensure adequate review of the protocol to determine compliance with the JHI Biosafety Program, local, state and federal regulations (Methods of Procedure or Experimental Protocol from a grant application will suffice). Please include information such as:

a) The purpose of the research;

b) An assessment of risks to personnel working with the agent or material;

c) An outline of the procedure and techniques to be employed;

d) Specifically describe the safe practices, equipment, and facilities that will be used to protect personnel from exposure to the agent or material;

e) Specifically describe methods of inactivation or disposal of the agent or contaminated materials.

15. I accept responsibility for the safe conduct of work with this material.

I will ensure that all personnel receive training in regard to proper safety practices and personal protective equipment needed for this work.

Principal Investigator: _____ Date: _____

Signature

MAIL OR FAX TO: Biosafety Division

Appendix C2 - IBC Research Registration Form

REGISTRATION OF RESEARCH WITH SELECT AGENTS

IBC #

DATE

BIOSAFETY LEVEL

ACTION

DO NOT WRITE IN ABOVE SPACE

APPLICATION MUST BE TYPEWRITTEN

1. Principal Investigator _____.

Academic Title _____ Social Security No. _____.

2. Department _____ Division _____.

3. Addresses: Office: _____ Lab: _____ Telephone # _____.

4. Project Title _____.

5. Name and source of select agent (list attached) _____.

6. Will you be doing only Clinical/Diagnostic work with this select agent? ( ) Yes ( ) No.

7. Will you be working with isolates/concentrates of this select agent? ( ) Yes ( ) No.

8. Will you use laboratory animals for any of your work with this select agent? ( ) Yes ( ) No.

9. Will you use large animals for any of your work with this select agent? ( ) Yes ( ) No.

10. Will you be doing any large scale "production level" work with this select agent? ( ) Yes ( ) No.

11. Are intact animals exposed to the select agent? ( ) Yes ( ) No.

Animal room where exposed animals are housed. _____.

12. Biologic containment level required: Biosafety Level # _____.

13. Attach a sketch/floor plan for laboratory where work will be performed – show entry, location of BSC, incubators, freezers, autoclaves, and other equipment specified for work with the agent.

14. Please list all professional personnel, employees and students involved in the project who will come into contact with the select agent:

NAME	**Mailing Address**	**Social Security No.**
_____	_____	_____

_____ _____ _____

_____ _____ _____

15. Describe briefly the type of work being done with this select agent. _____

_____.

16. Describe; 1) how you control access to laboratory where the select agent is used, 2) how you ensure adequate training for personnel working with the agent, 3) where you store the select agent, and 4) proposed method of disposal of select agent when work is complete. _____

_____.

17. Describe the air-handling system for the laboratory where the work will be performed (e.g., single pass or re-circulation, type of filters, method for handling safety cabinet exhaust. _____

18. I accept responsibility for the safe conduct of work with this material. I will inform all personnel of all hazards associated with this work and the level of biological containment required to perform this research safely.

Principal Investigator: _____ Date: _____.

Signature

SELECT AGENT LIST

☐ Viruses

1.Crimean-Congo haemorrhagic fever virus

2.Eastern Equine Encephalitis virus

3.Ebola viruses

4.Equine Morbillivirus

5.Lassa fever virus

6.Marburg virus

7.Rift Valley fever virus

8.South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)

9.Tick-borne encephalitis complex viruses

10.Variola major virus (Smallpox virus)

11.Venezuelan Equine Encephalitis virus

12.Viruses causing hantavirus pulmonary syndrome

13.Yellow fever virus

Exemptions: Vaccine strains may be exempt.

☐ Bacteria

1.Bacillus anthracis

2.Brucella abortus, B. melitensis, B. suis

3.Burkholderia (Pseudomonas) mallei

4.Burkholderia (Pseudomonas) pseudomallei

5.Clostridium botulinum

6.Francisella tularensis

7.Yersinia pestis

Exemptions: vaccine strains may be exempt.

☐ Rickettsiae

1.Coxiella burnetii

2.Rickettsia prowazekii

3.Rickettsia rickettsii

☐ Fungi

1.Coccidioides immitis

☐ Toxins

1.Abrin

2.Aflatoxins

3.Botulinum toxins

4.Clostridium perfringens epsilon toxin

5.Conotoxins

6.Diacetoxyscirpenol

7.Ricin

8.Saxitoxin

9.Shigatoxin

10.Staphylococcal enterotoxins

11.Tetrodotoxin

12.T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt.

☐ Recombinant organisms/molecules

1.Genetically modified microorganisms or genetic elements from organisms on this list, shown to produce or encode for a factor associated with a disease.

2.Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on this list, or their toxic subunits.

MAIL OR FAX TO: Biosafety Division

Appendix C3 - IBC Research Registration Form

REGISTRATION OF RESEARCH WITH RECOMBINANT DNA

IBC #

DATE

BIOSAFETY LEVEL

ACTION

DO NOT WRITE IN ABOVE SPACE

APPLICATION MUST BE TYPEWRITTEN

1. Principal Investigator _____.

Academic Title _____ Social Security No. _____.

2. Department _____ Division _____.

3. Addresses: Office: _____ Lab: _____ Telephone #

.

4. Project Title _____.

5. Source of DNA to be cloned (human/animal/microbial) _____.

6. If virus source, is it more than 2/3 of the viral genome? Yes ( ) No ( ).

7. Specify the gene sequence to be inserted into the recombinant (attach construct map).

_____.

8. Host or Environment (Cloning Vehicle) _____.

9. Is a Helper Virus used? No ( ) Yes ( ) If yes, a Retrovirus? Yes ( ) No ( ).

10. Vector(s)/Specific phage or plasmid _____.

11. Are intact animals exposed to the Recombinant? Yes ( ) No ( ).

Animal room where exposed animals are housed. _____.

12. Are mammalian cells exposed to the Recombinant? Yes ( ) No ( ).

Cell line source. _____.

13. Please circle relevant situation(s) that apply to your project:

Host / Environment		Biosafety Level
E. coli. K12	Yes/No	BSL1 / BSL2
Other Bacteria:	Yes/No	
Non-Pathogen	Yes/No	BSL1 / BSL2 / BSL3
Pathogen Risk 2	Yes/No	BSL2 / BSL3
Pathogen Risk 3	Yes/No	BSL2 / BSL3
Toxin Gene	Yes/No	BSL2 / BSL3
Drug Resistance Gene	Yes/No	BSL2 / BSL3
Yeast/YAC	Yes/No	BSL1 / BSL2
Tissue Culture Cells	Yes/No	
R-DNA/Plasmids	Yes/No	BSL1 / BSL2
Segment of Virus	Yes/No	BSL1 / BSL2 /BSL3
Virus Vector	Yes/No	BSL2 / BSL3

If Virus Vector: Adeno/AAV/Retro/Vaccinia/Other _____

Characterized/FDA or NIH Approved/Novel

Intact Lab Animal Recipient Yes/No

R-DNA/Plasmids	Yes/No	BSL1-N / BSL2-N
Transgenic	Yes/No	BSL1-N / BSL2-N

Virus Vector Yes/No BSL1-N / BSL2-N / BSL3-N

SCID/Nude Yes/No BSL1-N / BSL2-N / BSL3-N

If Whole Animal Recipients: Species

Has Institutional Animal Use & Care Committee been Notified? ( ) Yes ( ) No.

Human Subject Recipient Yes/No

R-DNA/Plasmid Yes/No BSL2 / BSL3

Pathogen Yes/No BSL2 / BSL3

Virus Vector Yes/No BSL2 / BSL3

If Human Subject Recipients: Has IRB been Notified? ( ) Yes ( ) No.

IRB Approval Number _____.

Plants/Insects Yes/No

Field Release Yes/No BSL2-P / BSL3-P

14. Is a deliberate attempt made to obtain expression of foreign gene(s) in the cloning vehicle?

Yes ( ) No ( ). If yes, what proteins, materials, or antigens? _____.

15. Give specific reference for your experiment from the NIH Recombinant DNA Guidelines

(Refer to the University Biosafety Manual (Leave blank if not sure): _____.

16. Biologic containment level required: Biosafety Level # _____.

17. Please list all professional personnel, employees and students involved in the project who will come into contact with these materials:

NAME	**Mailing Address**	**Social Security No.**
_____	_____	_____

_____ _____ _____

_____ _____ _____

18. Project Summary _____

_____.

19. I accept responsibility for the safe conduct of work with this material. I will inform all personnel of all hazards associated with this work and the level of biological containment required to perform this research safely.

Principal Investigator: _____ Date: _____.

Signature

MAIL OR FAX TO: Biosafety Division

Appendix C4 - IBC Research Registration Form

REGISTRATION OF RESEARCH WITH NON-HUMAN PRIMATES

(B-VIRUS & TB PRECAUTIONS)

IBC #

DATE

BIOSAFETY LEVEL

ACTION

DO NOT WRITE IN ABOVE SPACE

APPLICATION MUST BE TYPEWRITTEN

1. Principal Investigator _____

Academic Title _____ Social Security No. _____

2. Department _____ Division _____

3. Mailing Address _____ Telephone Number _____

4. Project Title _____

5. Please indicate housing location(s) for non-human primates.

Building(s) _____ Room(s) _____

6. Location where non-human primates and/or related materials will be utilized.

Building(s) _____ Room(s) _____

7. Please list all professional personnel, employees and students involved in the project who will come into contact with non-human primates or their products:

NAME **Mailing Address** **Social Security No.**

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

8. Please attach a description of the procedures for use of non-human primates, including precautions to be taken and methods used in handling blood, body fluids, tissue and excrement and how you plan to dispose of waste material.

9. I accept responsibility for the safe conduct of work with this material.

I will inform all personnel of the hazards associated with this work and the level of containment required to perform this research safely.

Principal Investigator: _____ Date:

Signature

MAIL OR FAX TO: Biosafety Division

Appendix C5 - IBC Research Registration Form

REGISTRATION OF RESEARCH WITH SHEEP AND GOATS

(Q FEVER PRECAUTIONS)

IBC #

DATE

BIOSAFETY LEVEL

ACTION

DO NOT WRITE IN ABOVE SPACE

APPLICATION MUST BE TYPEWRITTEN

1. Principal Investigator _____

Academic Title _____ Social Security No. _____

2. Department _____ Division _____

3. Mailing Address _____ Telephone Number _____

4. Project Title _____

5. Please indicate housing location(s) for sheep (including lambs) or goats.

Building(s) _____ Room(s) _____

6. Location where sheep (including lambs) or goats and/or related materials will be utilized.

Building(s) _____ Room(s) _____

7. Please list all professional personnel, employees and students involved in the project who will come into contact with sheep (including lambs), goats or their products:

NAME	Mailing Address	Social Security No.
_____	_____	_____
_____	_____	_____
_____	_____	_____

8. Please attach a description of the procedures for use of sheep or goats, including precautions to be taken and methods used in handling products of conception and excrement and how you plan to dispose of waste material.

9. I accept responsibility for the safe conduct of work with this material.

I will inform all personnel of the hazards associated with this work and the level of containment required to perform this research safely.

Principal Investigator: Date:

Signature

MAIL OR FAX TO BIOSAFETY DIVISION

Appendix D1 – Potential Pathogenic Material Research Update Letter

DATE

MEMORANDUM

TO: Dr. «FSTNAMEPI» «LSTNAMEPI»

«DEPARTMENT»

«ADDRESS» «INSTITUT»

FROM: Biosafety Officer

SUBJECT**: Annual Update of Potentially Pathogenic Material Research Project**:

«TITLE»

- According to our records, your research project, listed above, needs an annual update for the Institutional Biosafety Committee.
- Please change any inaccurate information, fill in any blanks, sign, and return this memorandum.
- If your project is complete or not funded, please indicate this when you return the memorandum.
- When major changes have occurred with this project, we will fax over a new registration form for you to fill out and return.

PLEASE CHECK THE ACCURACY OF THE FOLLOWING INFORMATION

Principal Investigator**:** Dr. «FSTNAMEPI» «LSTNAMEPI»

Social Security Number: «SOCSECNO» Laboratory Address: «LABS»

Telephone No.: «TELEPHONE»

IBC Registration #: «REGISTRNO»

Last Date Registered or Updated Project: «LSTREG»

Project Title: «TITLE»

Potential Pathogen or Material: «AGENT»

Biosafety Levels > Facilities: BSL «FACBL»Practices: BSL «PRABL»

Personnel Working on the Project:

«PERSONNEL»

Are Animals Used? Species_____ Animal Housing Bldg. & Room No._____

THE INFORMATION ON THIS FORM IS CORRECT OR HAS BEEN CORRECTED:

Signature: _____ Date: _____

Please FAX OR MAIL this memo to: Biosafety Officer

Appendix D2 – Recombinant DNA Research Update Letter

DATE

MEMORANDUM

TO: Dr. «FSTNAMEPI» «LSTNAMEPI»

«DEPARTMENT»

«ADDRESS» «INSTITUT»

FROM: Biosafety Officer

SUBJECT: **Annual Update of Recombinant DNA Project:**

«TITLE»

- According to our records, your research project, listed above, needs an annual update for the Institutional Biosafety Committee.
- Please change any inaccurate information, fill in any blanks, sign, and return this memorandum.
- If your project is complete or not funded, please indicate this when you return the memorandum.
- When major changes have occurred with this project, we will fax over a new registration form for you to fill out and return.

PLEASE CHECK THE ACCURACY OF THE FOLLOWING INFORMATION

Principal Investigator: Dr. «FSTNAMEPI» «LSTNAMEPI»

Social Security Number: «SOCSECNO» Laboratory Address: «LABS»

IBC Registration #: «REGISTRNO»

Last Date Registered or Updated Project: «LSTREG»

Project Title: «TITLE»

NIH Guideline: «NIHREF»

Biosafety Levels > Facilities: BSL «FACBL»; Practices: BSL «PRABL»

Personnel Working on the Project:

«PERSONNEL»

THE INFORMATION ON THIS FORM IS CORRECT OR HAS BEEN CORRECTED:

Signature: _____ Date:

Please FAX OR MAIL to: Biosafety Officer

Appendix E1 – Potential Pathogenic Material Research Registration Letter

DATE

MEMORANDUM

TO:Dr. «FSTNAMEPI» «LSTNAMEPI»

«DEPARTMENT»

«ADDRESS» «INSTITUT»

FROM: Biosafety Officer

SUBJECT: Registration of Recombinant DNA; IBC # **«REGISTRNO»**

PROJECT TITLE: «TITLE»

NIH GUIDELINE REFERENCE: «NIHREF» IBC APPROVAL DATE:

«IBC_APROV»

BIOSAFETY LEVEL: Facilities «FACBSL»; Practices «PRABSL»

The Biosafety Division has registered your project. Please note; if you have "Pending" next to the above IBC APPROVAL DATE, you are not approved to begin this

research project. You must have an IBC Approval Date before research can begin. This memorandum acknowledges your registration in case you need it for your grant application.

Please note that your project has a unique Institutional Biosafety Committee (IBC) Registration Number. This number will change each year when we update your project. Please use this number in your correspondence with us. You may register additional recombinant DNA projects by filling out a new registration form intranet web site.

We will update your project annually. Around the anniversary month of your project registration, we will send you an update letter. Please make any changes to your project, laboratory or office location, changes among personnel, etc., and return the form to me.

Health, Safety and Environment will carry out periodic inspections. This will assure compliance with work practices and laboratory facility design appropriate for the level of biosafety assigned to your project.

Please call or email the Biosafety Officer if you have any questions or need additional forms. You may also fill out and print an online form located at the intranet web site. We look forward to working with you.

Appendix E2 – Recombinant DNA Research Registration Letter

DATE

MEMORANDUM

TO:Dr. «FSTNAMEPI» «LSTNAMEPI»

«DEPARTMENT»

«ADDRESS» «INSTITUT»

FROM: Biosafety Officer

SUBJECT: Registration of Recombinant DNA; IBC # **«REGISTRNO»**

PROJECT TITLE: «TITLE»

NIH GUIDELINE REFERENCE: «NIHREF» IBC APPROVAL DATE:

«IBC_APROV»

BIOSAFETY LEVEL: Facilities «FACBSL»; Practices «PRABSL»

The Biosafety Division has registered your project. Please note; if you have "Pending" next to the above IBC APPROVAL DATE, you are not approved to begin this

research project. You must have an IBC Approval Date before research can begin. This memorandum acknowledges your registration in case you need it for your grant application.

Please note that your project has a unique Institutional Biosafety Committee (IBC) Registration Number. This number will change each year when we update your project. Please use this number in your correspondence with us. You may register additional recombinant DNA projects by filling out a new registration form available at the intranet web site.

We will update your project annually. Around the anniversary month of your project registration, we will send you an update letter. Please make any changes to your project, laboratory or office location, changes among personnel, etc., and return the form to me.

Health, Safety and Environment will carry out periodic inspections. This will assure compliance with work practices and laboratory facility design appropriate for the level of biosafety assigned to your project.

Please call or email the Biosafety Officer if you have any questions or need additional forms. You may also fill out and print an online form located at the intranet web site. We look forward to working with you.

Appendix F - Employee Training Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database and the formatting has been left off to save space.

Table Cost Centers

- Column COSTCENTERCODE
- Column COSTCENTERNAME

Table Course Name

- Column COURSECODE (###)
- Column COURSENAME

Table Courses Attended

- Column SOCIALSECURITYNUMBER
- Column COURSECODENUMBER
- Column TRAININGDATE
- Column INSTRUCTOR
- Column DATEENTERED

Table Demographic Update Record

- Column INPUTDATE
- Column DEMOGRAPHICGROUP
- Column RECORDCOUNT
- Column ERRORCOUNT

Table Department Name

Column DEPARTMENTCODE

Column DEPARTMENTNAME

Column DIVISIONNAME

Column CLINICALDEPARTMENT (Y/N)

Table Division Name

Column DIVISIONCODE

Column DIVISIONNAME

Column CAMPUSLOCATION

Table Employee Address

Column SOCIALSECURITYNUMBER

Column ORGANIZATION

Column ADDRESS1

Column ADDRESS2

Column CITY

Column STATE

Column ZIP

Column PHONE

Table Employee Department

Column SOCIALSECURITYNUMBER

Column ORGANIZATION

Column HIREDATE

Column TERMINATIONDATE

Column DEPARTMENT

Column COSTCODE

Column POSITIONCLASSIFICATIONNUMBER

Column TITLE

Column ARCHIND

Column FULLPARTTIMEINDICATOR

Column SHIFT

Table Identification Only

Column NAME

Column SEX

Column BLOODBORNEPATHOGENINDICATOR

Column DEPARTMENTADMINISTRATOR (Y/N)

Table Instructors

Column INITIALS

Column INSTRUCTOR

Table JHH Bloodborne Pathogen Group

Column POSITIONCLASSIFICATIONNUMBER

Column TITLE

Column CATEGORY (ATTENDEDSESSION/NURSINGSTAFF)

Table MD Physician Information

Column SOCIALSECURITYNUMBER

Column STATEREGISTRATIONNUMBER

Column CATEGORY

Column COMMITTEEACTIONINDICATOR

Column STATESTATUS (ACTIVE/INACTIVE)

Column PROVISIONALINDICATOR

Table Object Definition

Column IDENTIFICATIONNUMBER

Column PARENTINDENTIFICATIONNUMBER

Column NAME

Column OBJECTTYPE

Column EXTRA1

Column EXTRA2

Table Organization Name

Column ORGANIZATIONCODE

(UNIVERSITY/HOSPITAL/HEALTHSYSTEM/ETC.)

Column ORGANIZATIONNAME

Table Physician Categories

Column CATEGORY (FULLTIME/PARTTIME/HOUSESTAFF/ETC.)

Column TITLE

Column CATEGORYGROUP (ACTIVE/HOUSESTAFF/CLINICAL/ETC.)

Table Unrecordable Training

Column KEYNUMBER

Column SOCIALSECURITYNUMBER

Column NAME

Column COURSECODENUMBER

Column TRAININGDATE

Column DEPARTMENT

Column ADDRESS

Column INSTITUTION

Column DATEENTERED

Appendix G - BSC & CAB Certification and Service Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database

Serial Number (indexed)

Construction Contract Number

Equipment Room Number

Equipment Building

Barcode Number

Contact Last Name

Contact First Name

Contact Room Number

Contact Building

Principal Investigator Name

Principal Investigator Department

Principal Investigator Room Number and Building

Institution

Telephone

BSC or CAB

Manufacturer

Model

Service Performed

Blower Motor % Speed

Priority (emergency, routine)

Service Call Date

Service Date

Certification Payment Method

Certification Payment Date

Certification Date

Invoice Number

Disputes

HEPA Filter Payment

HEPA Filter Change Date

Pre-filter Status

Ultraviolet Lamp & Non-contract Payment Date

Ultraviolet Lamp & Non-contract Repair Date

Other Payments

Other Dates

Part Replacement

Notes

Comments

Laboratory Contact Name

Thimble Connection (Y/N)

Appendix H - BSC & CAB Certification Renewal Letter

MEMORANDUM

Date

To: «FSTNAME» «LSTNAME»

«DEPARTMENT»

«OWNRADDRS»

«MAILROOM»

From: Biosafety Office

Subject**: Annual certification of Biological Safety Cabinet BSC or Clean Air Bench CAB**

Your BSC or CAB listed below is due for required annual or semi-annual certification.

University Departments: Please send me a Materials and Services Request Form for this work. Please include the Serial Number, Room Number, and Contact Person for the BSC or CAB to be certified.

Hospital departments: Please send a check for the full amount, payable to Biosafety Division . Please include the Serial Number, Room Number, and Contact Person for the BSC or CAB to be certified.

Payment must be received before certification of your unit can be scheduled. You will be contacted to schedule the required service.

Certification costs are: BSC = $xxxxx or CAB = $xxxxx

Payment entitles you to annual performance testing, free labor and replacement parts (fluorescent lights, switches, motors, etc. by contacting the Biosafety Division). Filters and UV lights must be paid for at the time of replacement.

Please check the accuracy of the information below and make any changes on this memorandum. Or email to contact@yourorganization.com

Last Certification Date:	«CERTDATE»
Equipment Type:	«CABINET»
Manufacturer:	«MANUFACTUR»
Model Number:	«MODELNO»
Serial Number:	«SERIALNO»
Location of BSC/CAB:	«ROOMNUMBER» «BUILDING»
Laboratory Phone Number:	«PHONENO»

Please attach payment and send to the Biosafety Division for scheduling

Appendix I - Portable HEPA Unit Service Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database

Identification Number

Serial Number (indexed)

Barcode Number

Manufacturer

Model

Pre-filter Size

Pre-filter Change Date

Call for Service Date

Service Date

HEPA Filter Size

HEPA Filter Change Date

Parts

Magnehelic Gauge Reading

Comments

Location Date

Room Number

Building

Mailstop

Contact Name

Contact Telephone

Appendix J - PAPR Service Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database

Identification Number

Serial Number (indexed)

Barcode Number

Manufacturer

Model

Service Call Date

Service Date

HEPA Filter Size

HEPA Filter Change Date

Airflow OK Date

Battery Charged Date

Parts

Comments

Location Date

Room Number

Building

Contact Name

Telephone

Appendix K - Bag-In Bag-Out Service Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database

Identification Number

Barcode

Building

Location

Contact Name

Contact Address

Additional Contact Names

Institution

Telephone

Manufacturer

Housing Model

In Use (Y/N)

Exhaust Fan Number

Pre-filter Number

Pre-filter Size

Pre-filter Bag Number

Pre-filter Change Date

HEPA Filter Number

HEPA Filter Size

HEPA Filter Bag Number

HEPA Filter Change Date

Charcoal Filter Number

Charcoal Filter Size

Charcoal Filter Bag Number

Charcoal Filter Change Date

Magnehelic Gauge 1 Reading

Magnehelic Gauge 1 Reading Date

Magnehelic Gauge 1 Configuration

Magnehelic Gauge 1 Range

Magnehelic Gauge 2 Reading

Magnehelic Gauge 2 Reading Date

Magnehelic Gauge 2 Configuration

Magnehelic Gauge 2 Range

Magnehelic Gauge 3 Reading

Magnehelic Gauge 3 Reading Date

Magnehelic Gauge 3 Configuration

Magnehelic Gauge 3 Range

Service Call Date

Service Date

Invoice Date

Invoice Amount

Parts

Comments

Source

Appendix L - IBC Research Registration Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database

Registration Number (A, B, OR DYYMMDD####)

Principal Investigator Last Name (indexed)

Principal Investigator First Name (indexed)

Academic Title

Department

Institution (School)

Room Number

Building

Telephone

Social Security Number

Lab Address

NIH Recombinant Guideline Reference

Facility Biosafety Level

Practices Biosafety Level

BSL-3 Lab Inspection Date

Non-Exempt (Y/N)

Personnel Names

Project Title

Potential Pathogen

Animals

Animal Committee Registration Number

First Registration Date

Last Registration Date

Comments

IBC Approval Date

Select Agents Involved

Print Record (p)

Appendix M - IBC Select Agent Registration Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database

Registration Number

Select Agent Certification Number

Principal Investigator Last Name (indexed)

Principal Investigator First Name (indexed)

Academic Title

Department

Institution (School)

Room Number

Building

Telephone

Fax

Email

Social Security Number

Lab Room Number

Lab Building

Lab Diagram

Facility Biosafety Level

Practices Biosafety Level

Application Sent Date

Application Complete Date

Exempt

Biosafety Officer Inspection Date

Select Agent Class

Select Agent Name

Quantity

Agent Storage Method

Agent Disposal Method

Clinical or Diagnostic Use (Y/N)

CLIA (Y/N)

If Toxin Class, Recombinant DNA (Y/N)

Animals

Large Animals (Y/N)

Animal Location

Large Scale (Y/N)

Personnel Names

Project Title

First Registration Date

Last Registration Date

Comments

IBC Approval Date

CDC Inspection Date

Print Record

Appendix N - Shipping Certification Training Database

Microsoft Access 97© File (column) names

Filenames are truncated in the database

Social Security Number (indexed)

Last Name

First Name

Department

Room Number

Building

Institution

Training Date

Training Location

Instructor

Pre- & Post-Test Scores

Appendix O - Johns Hopkins Institutions BSL-3 Specifications

BIOSAFETY LEVEL 3 DESIGN SPECIFICATIONS:

Design Component	Description
Sealed room	Laboratory must be effectively air and liquid tight. Air must pass easily under and around the door of the containment laboratory.
Air Monitoring	Recommend a one inch circular cut out in the containment laboratory door with a vertically mounted ribbon to indicate directional air flow into the containment laboratory. Pressure monitors are not recommended.
Location	Laboratory is restricted from general traffic by access through two sets of doors. First, an anteroom (change area) and then into the laboratory through a card access lock.
Flooring	Seamless or welded vinyl coving with an integral cove, sealed to flooring material with silicone.
Walls	Material should be washable and resistant to cleaning agents and disinfectants. Tile, Formica or epoxy paint are acceptable.

Ceiling Monolithic construction, recommend gypsum board with a finish material similar to above. Removable tiles and drop ceiling tiles unacceptable. Access to utilities via air tight ceiling panel.

Doors Self-closing and open inward.

Windows (if any) Permanently sealed shut.

Plumbing Horizontal and sealed with fire-retardant caulk. Wall and ceiling penetrations are minimal. No floor penetrations.

Vacuum Utility Separate and independent from house vacuum system.

Electrical Utility All outlets, fixtures, junction boxes and conduit must be surface mounted. Wall and ceiling penetrations are minimized.

Laboratory Work Surfaces Made of materials resistant to cleaning and disinfecting agents. Sturdy furnishings spaced to permit cleaning and maintenance. Impervious to water. Resistant to acids, alkalis, organic solvents and moderate heat.

Hand Washing Sink Located near exit. Operated infrared , wrist, elbow or foot control.

Emergency Eye, Face and Located near exit proximate to sink. Recommend Speakman Model SE921 or equivalent connected to cold, potable water supply. An ANSI approved eyewash should also be installed.

Autoclave Double door model installed between glassware prep area or anteroom. Drain must be inside the containment laboratory with a bioseal between the containment laboratory and the non-containment area. High air velocity exhaust canopies should be installed above each autoclave door. Floor penetration for drain must be sealed or covered with a HEPA filtered cabinet.

Ventilation Ten to 12 ACPH, no recirculation, constant volume 24 hours per day. Supply and exhaust ducts in the containment laboratory must contain 100% shut off dampers to isolate laboratory air from other areas of the building. Exhaust is not to be recirculated to any other part of the building. Ducted exhaust must be discharged through redundant bag in bag out roof top housings with dedicated primary and secondary back-up fans. Each bag in bag out housing should contain pre-filters and HEPA filters with magnehelic gauges (with air vent valves) between the pre-filer housing and the HEPA filter housing.

Biological Safety Cabinets Class II, Type B3 BSC spaced three to six inches out from the rear wall. HEPA filtered exhaust shall be connected to the laboratory exhaust system with a flexible eight- or ten-inch plastic duct and an air volume control damper for each BSC. The flexible duct shall be connected to a thimble exhaust connection (JHU

specifications available). The thimble exhaust shall be adjusted to capture 1.5 times the manufacturer's rated exhaust airflow from the BSC. Space near the ceiling will be required to permit opening of TEC panels. All utility connections supplied to the BSC shall be installed under the BSC. A gas shut off valve (with handle) shall be provided on the right or left side the BSC that can be reached by a seated operator. The gas supply line shall have a pipe union between the shut off valve and the connection to the BSC. Specific JHU performance specifications (available) are required for BSC's.

Flammable Storage Cabinet Shall be vented through a chemical fume hood with a pipe extending from a fire arrestor screen at the rear of the flammable storage cabinet and extending behind and four inches above the bottom of the rear baffle.

Air Pressure Differentials The anteroom shall be at 100 cfm negative with respect to an adjoining space. The containment laboratory shall be at least 100 cfm negative with respect to the anteroom.

Directional Airflow Supply and exhaust shall be located to ensure airflow from areas of least potential hazard toward areas of greatest potential hazard.

Supply Vents The vents shall be four-way, three-way, two-way or one-way, depending on the location of areas of greatest hazard. Low velocity spiral vents are preferred to standard directional vents. Vents shall be directed away from the face of BSC's, fume hoods, and incubators.

Appendix P - BSL-3 Standard Operating Procedures Outline

TABLE OF CONTENTS

Waste disposal procedures

Biohazardous spill control

- Large spill outside of BSC
- Small spill outside of BSC

Radioactive spill outside of BSC

- Spill outside the research facility

Autoclave quality assurance program

Resources for pathogen exposures

Appendix Q - Laboratory Survey Checklist

UNIVERSITY LABORATORY SURVEY FIELD REPORT

Department _____ Bldg_____ Room_____

P.I. _____ Phone_____ Date_____

Surveyor _____ Departmental Representative_____

Door Signage	**Corrected**
_____ Warning labels missing (list)_____	_____
_____ Emergency contact information missing _____	_____
_____ Refrigerator signage missing (list)_____	_____

Improper Handling / Storage

_____ Improperly labeled or unlabeled chemicals or materials (list)_____	_____
_____ Incompatible chemicals stored together _____Flammables / Corrosives,	_____
_____ Organics / Oxidizers	_____
_____ Acids / Bases not segregated	_____
__Flammable material in non-approved __Cabinet__ Refrigerator_ Cold-room.	_____
_____ Undated or outdated chemicals (list)_____	_____
_____ Flammable solvents _____ > 10 gal outside flam. cab.	_____

_____ containers > 1 gal outside flam. cab. _____

_____ Unsecured Gas Cylinders _____

Improper Waste Handling

_____ Unapproved or inappropriate container:

__ Sharps __ Lab Waste __ Autoclave Waste __Chemicals _____

_____ Over filled Container:

__ Sharps __ Lab Waste __ Autoclave Waste __Chemicals _____

Safety/ Emergency Equipment

_____ BSC / CAB Serial #-_____ Certification not current _____

_____ BSC / CAB work area cluttered _____ _____

_____ Chemical Fume Hood __ Certification not current __ baffle/ slot blocked _____

_____ Personal Protective equipment not being used (specify _____) _____

_____ Fire alarms blocked _____

_____ Fire extinguisher ___blocked, ___missing, ___not maintained, _____ _____

_____ Safety shower ___blocked, ___inaccessible ___due for inspection _____

_____ Eyewash ___blocked, ___water pressure not proper, _needed _____

Other / Comments

____ Improper attire: Specify _____

____ Evidence of food or drink in the laboratory: Specify _____

____ Improper electrical devices: Specify _____

____ Vacuum line filter absent _____

____ Paper Towels missing _____

____ Hand Soap missing or not appropriate _____

____ Cosmetics on the open bench _____

____ Other comments _____