DATE: March 25, 2002

TO: All Schools, Centers and Divisions of the University

SUBJECT: Institutional Biosafety Committee (IBC) & Biosafety Program

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**I. POLICY**

Saint Louis University endeavors to provide safeguards for research activities utilizing biohazardous materials so as to prevent the release of agents that could harm students, employees, the public, or the environment. Biological agents coming under this policy include bacteria, viruses, rickettsia, parasites, prions, and fungi as well as toxins,
deoxyribonucleic acid (DNA), and ribonucleic acid (RNA), known to be, or suspected of being, hazardous to humans, plants or animals. Also covered are certain experiments utilizing organisms in which DNA from another species has been incorporated into the genome of the organism. To meet these important safety objectives, the University has established an Institutional Biosafety Committee (IBC) to provide for review of research involving biohazards, recombinant DNA, and Gene Therapy.

II. SCOPE OF POLICY

This policy extends to research facilities within all divisions and departments of Saint Louis University that employ agents that are:

1. Pathogenic to humans, plants or animals if released into the environment, including all select agents; OR

2. Biological organisms into which certain foreign DNA has been incorporated so as to cause the use of these transformed organisms to be regulated by the Guidelines of the Office of Biotechnology Activities (OBA) of the National Institutes of Health (NIH) by requiring approval of an experiment by a local committee or by OBA’s Recombinant DNA Advisory Committee (RAC), prior to its initiation. These organisms include but are not limited to those used in research or clinical investigations involving:

   a. Recombinant DNA molecules (rDNA)
   b. Gene Therapy

Laboratories engaged in only clinical diagnosis and evaluation of patients are exempt from this policy except for Section XII if they operate under an infection control plan that meets the requirements of the Occupational Safety and Health Administration (OSHA) Blood-borne Pathogens Standard (29 CFR Part 1910.1030).

The breadth of the information and requirements contained in this policy extends to all references cited within this document.

III. AUTHORITY & IMPLEMENTATION

The President of the University has conferred upon the Provost the authority to appoint an Institutional Biosafety Committee (IBC) for Saint Louis University. The IBC reports to the Associate Provost for Research Administration through the IBC Chairperson. The authority to comprehensively review, and approve or disapprove, the biological safety aspects of any research or clinical protocol are vested in the IBC. The IBC also serves as a technical resource for the biological safety program, including but not limited to:
1. The drafting, review, approval and implementation of specific biological safety procedures, policies, manuals, and other documents intended to serve as tools in implementing the biological safety program.

2. The implementation and enforcement of the biological safety program by the Biological Safety Officer (BSO), working under the authority of and reporting through the Director of Environmental Safety to the Associate Provost for Research Administration.

IV. KEY WORDS & TERMS (Adapted from OBA, CDC and other sources)

- **Biological Agent:** Any bacteria, viruses, rickettsia, parasites, prions, fungi, toxins, deoxyribonucleic acid (DNA), and ribonucleic acid (RNA), including any recombinant DNA or RNA, known to be, or suspected of being, hazardous to human, plants, and animals.

- **Biological Safety Officer (BSO):** An individual appointed by the University to oversee management of Biosafety risks and implementation of the Biosafety Program. The Biological Safety Officer, a full-time position within the Saint Louis University Office of Environmental Safety & Services, is a member of the IBC and serves as the Executive Secretary of the IBC.

- **Biosafety Level (BSL):** A description of the degree of physical containment required to be employed to confine biohazardous organisms, including those containing recombinant DNA molecules, to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. Biosafety levels are graded from BSL-1 (the least stringent) to BSL-4 (the most stringent).

- **BMBL:** Common abbreviated term for CDC/NIH publication: *Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, 1999.*

- **CDC:** The Department of Health and Humans Services’ Centers for Disease Control and Prevention.

- **DHHS:** U.S. Department of Health and Human Services

- **Institutional Biosafety Committee (IBC):** A University committee created consistent with NIH Guidelines to review research involving recombinant DNA, Gene Therapy, and other research that entails biohazard risks.

- **NIH:** National Institutes of Health. The NIH is one of several health agencies within the Public Health Service, which is an agency within the U.S. Department of Health and Human Services (DHHS).
• **NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines):** The NIH guidelines outline principles for the safe conduct of research employing recombinant DNA technology. The NIH Guidelines detail practices and procedures for the containment of various forms of recombinant DNA research, for the proper conduct of research involving genetically modified plants and animals, and for the safe conduct of human gene transfer research. Originally created in 1976, the NIH Guidelines are a “living document” that is periodically revised to keep pace with the changing state of science. *Although not regulatory by definition, compliance with the NIH Guidelines is mandatory for investigators at Saint Louis University due to NIH funding of research at Saint Louis University.* Failure to follow the NIH Guidelines by one investigator can lead to suspension or termination of NIH funding for all NIH sponsored programs at Saint Louis University.

• **Office of Biotechnology Activities (OBA):** The NIH office responsible for developing, implementing, and monitoring NIH policies and procedures for the safe conduct of recombinant DNA activities, including human gene transfer (gene therapy).

• **Recombinant DNA Advisory Committee (RAC):** An NIH advisory committee whose principal role is to provide advice and recommendations to the NIH Director on (1) the conduct and oversight of research involving recombinant DNA, including the content and implementation of the NIH Guidelines, and (2) other NIH activities pertinent to recombinant DNA technology. A major element of this role is to examine the science, safety and ethics of clinical trials that involve the transfer of recombinant DNA to humans.

• **Recombinant DNA guidelines:** See NIH Guidelines for Research Involving Recombinant DNA Molecules.

• **Recombinant DNA molecules:** Under the current NIH Guidelines, these are molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from their replication. Refer to NIH Guidelines, at the following WEB site, for further details: [http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html)

• **Responsible Facility Official (RFO):** The Responsible Facility Official (RFO) is the University position that is authorized to transfer and receive select agents on behalf of the University researchers. The RFO has been designated as the primary contact for compliance with the Select Agent Rule, including the registration of select agents with the CDC. The Saint Louis University Biological Safety Officer is designated as the RFO at Saint Louis University.
**Restricted Person:** As defined in the USA PATRIOT Act, an individual that meets any one of the following criteria:
- A person who is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- A person who has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
- A person who is fugitive from justice;
- A person who is an unlawful user of any controlled substance;
- A person who is an alien illegally or unlawfully in the United States;
- A person who has been adjudicated as a mental defective or has been committed to any mental institution;
- A person who is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; currently these countries are:
  - Cuba
  - Iran
  - Iraq
  - Libya
  - North Korea
  - Syria
  - Sudan
- A person who has been discharged from the Armed Services of the United States under dishonorable conditions.

**Risk Groups (RGs):** Categories of biological agents based on their relative pathogenicity for healthy adult humans, as defined in the NIH Guidelines, that are used in making risk assessments, according to the following criteria:
- **Risk Group 1 (RG1)** agents are not associated with disease in healthy adult humans.
- **Risk Group 2 (RG2)** agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available.
- **Risk Group 3 (RG3)** agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available.
- **Risk Group 4 (RG4)** agents are likely to cause serious lethal human disease for which preventive or therapeutic interventions are *not usually* available.
Refer to NIH Guidelines, available at the following WEB site, for further details: [http://www4.od.nih.gov/oba/rae/guidelines/guidelines.html](http://www4.od.nih.gov/oba/rae/guidelines/guidelines.html)

**Select Agent:** Any one of a number of microorganisms (bacterium, viruses, fungi, and rickettsia) or toxins listed in 42 CFR 72.6: *Additional Requirements for Facilities Transferring or Receiving Select Agents (CDC).* The term also includes any genetically modified microorganisms or genetic elements from the listed organisms that are shown to produce or encode for a factor associated with a disease, and genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the listed toxins. Anticipated use...
of any select agents involving importation to Saint Louis University, or exportation from Saint Louis University, requires registration with the CDC in advance.

- **Select Agent Rule**: Regulations (42 CFR Part 72) that became effective on April 15, 1997 as a result of federal legislation (Antiterrorism and Effective Death Penalty Act of 1996), delineating a number of select agents (see “select agents” above) that are of potential use to terrorists, and which must be registered with the CDC prior to importation to the University or exportation from the University. Noncompliance with the Select Agent Rule can result in loss of NIH funding, as well as civil penalties. *IMPORTANT! See the following WEB link for important details that may be applicable to your research:*  
  http://www.cdc.gov/od/ohs/lrsat.htm

V. **BIOLOGICAL SAFETY OFFICER**

The Saint Louis University Biological Safety Officer, employed in the Office of Environmental Safety, oversees the management of biosafety risks. The Biological Safety Officer’s duties include, but are not limited to:

1. Periodic inspection to ensure that laboratory biological safety standards are rigorously followed.
2. Reporting to the IBC and the Director of Environmental Safety any significant problems, violations of the NIH guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator.
3. Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving biohazard agents, including select agents, and recombinant DNA research.
4. Providing advice on laboratory security.
5. Providing technical advice to Principal Investigators and the IBC on research safety procedures.
6. Serving as the “Responsible Facility Official” in assuring investigator and University compliance with the Select Agent Rule, and any amendments thereto.
7. Preparation and filing of annual IBC membership report to NIH/OBA.

VI. **COMMITTEE MEMBERSHIP**

Appointments made to the Institutional Biosafety Committee by the Provost shall include at least five members so selected that they collectively have experience and expertise in Biohazard control and recombinant DNA technology and the capability to assess the safety of research involving biohazardous agents (inclusive of all select agents), as well as recombinant DNA research, including human gene transfer trials, and to identify any
potential risk to public health or the environment. The Committee membership shall include:

1. **Animal Containment Expertise**: At least one individual with expertise in animal containment principles.
2. **Biological Safety Officer**: The University’s Biological Safety Officer, who is an individual trained and experienced in microbiological techniques, and related safety procedures. The BSO serves as the Executive Secretary of the IBC.
3. **Clinical Microbiology**: There shall be at least one representative from the Clinical Microbiology Laboratory.
4. **Community Representatives**: At least two members not otherwise affiliated with the University who represent the interests of the surrounding community with respect to health and protection of the environment. The extra-University members should be knowledgeable in the basic principles of microbiology and of recombinant DNA technology or capable of assimilating these principles within the context of their applicability to the surrounding community and the general public.
5. **Director of Environmental Safety**: The University’s Director of Environmental Safety, who is responsible for overall implementation of University safety programs as relates to protection of workers and the surrounding community from environmental risks.
6. **Infection Control**: At least one member shall have expertise in infection control.
7. **Plant Expertise**: At least one individual with expertise in plant, plant pathogen, or plant containment principles; if research is to be conducted involving recombinant DNA in plants.
8. **Research Scientists**: There shall be three or more research scientists with expertise in recombinant DNA technology, biological safety, and physical containment in order to ensure the competence necessary to review and approve recombinant DNA activities.
9. **Research Technical Staff**: There shall be at least one member representing the laboratory technical staff.
10. **Other ad hoc Members/Consultants**: Additional individuals knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment will be utilized as consultants or ad hoc members of the committee on an as-needed basis.

**Chairperson and Vice Chairperson**: the Provost shall appoint a Committee Chairperson and a Vice Chairperson. The Vice Chairperson shall be selected from amongst the members to fulfill the role of Acting Chairperson if the Chairperson is not available.

**Annual Report to NIH/OBA**: The Biological Safety Officer, on behalf of Saint Louis University and the IBC, shall file an annual report with NIH/OBA which includes:
1. A roster of all IBC members clearly indicating the Chairperson, contact person, Biological Safety Officer, plant expert (if applicable), animal expert, human gene therapy expert or ad hoc consultant (if applicable).
2. Biographical sketches of all IBC members, including community members.
VII. **IBC MEETING FREQUENCY**

1. **Regular Meetings:** In order to facilitate expeditious review of research investigator protocol applications, and to conduct other committee business, the IBC shall have regularly scheduled meetings, at least quarterly.

2. **Ad hoc Meetings:** To enhance expeditious review of research protocol application submissions or resubmissions between regularly scheduled meetings, ad hoc meetings will be scheduled as practical, taking into consideration IBC membership availability.

3. **Cancellation of Regular Meetings:** In the event there is no committee business to discuss, the regularly scheduled IBC meeting may be cancelled prior to the meeting without notice to the University community. Notwithstanding cancellation of a regularly scheduled meeting, Ad hoc meetings will be scheduled if needed.

4. **Quorum:** A quorum is required in order to conduct routine committee business. In order to establish a quorum:
   a. The number of committee members present must equal one more than half of the total committee membership;
   b. The Committee Chairperson or Vice Chairperson must be present;
   c. The Biological Safety Officer or the Director of Environmental Safety must be present; and
   d. At least one community representative must be present.

VIII. **IBC REVIEW FUNCTIONS**

The IBC functions to review research involving biohazard agents. The IBC also reviews recombinant DNA research conducted at or sponsored by Saint Louis University for compliance with the NIH Guidelines, and approves those research projects that are found to conform with the NIH Guidelines. The review shall include:

1. Independent assessment of the Biosafety containment levels required by the BMBL and/or NIH Guidelines, as applicable.

2. Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in biohazard and/or recombinant DNA research.

3. For human gene therapy:
   a. Ensuring that all aspects of Appendix M (*Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Research Participants*) of the NIH Guidelines have been appropriately addressed by the Principal Investigator.
   b. Ensuring that no research participant is enrolled in a human gene transfer experiment until the RAC review process has been completed.
   c. For human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator’s response to the RAC recommendations.
d. Ensuring that final IBC approval is granted only after the RAC review process has been completed.
e. Ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines.

4. Notifying the Principal Investigator of the results of the IBC’s review and approval.

5. Periodically reviewing biohazard and recombinant DNA research conducted at the institution to ensure compliance with OSHA requirements and the NIH Guidelines.

6. Adopting emergency plans covering accidental spills and personnel contamination resulting from biohazard and recombinant DNA research.

7. Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator.

IX. RESEARCH PROTOCOL APPLICATION SUBMISSIONS, REVIEWS, & APPROVALS

1. Investigator Review: Prior to undertaking research with a biological agent, it is the obligation of the principal investigator to evaluate the hazards of the agent(s) that will be used.
   a. A primary reference for organisms that are pathogenic to man is the most recent edition of the Center for Disease Control-National Institutes of Health publication: *Biosafety in Microbiological and Biomedical Laboratories*.
   b. For organisms that might be pathogenic to warm-blooded, nonhuman species the investigator is advised to consult with the veterinary pathologist of the Department of Comparative Medicine.
   c. Before using a vector to incorporate foreign genomic material, a copy of the latest Guidelines for Research Involving Recombinant DNA Molecules must be consulted.
   d. If the experiment involves use of an organism pathogenic to man, the principal investigator must request a copy of the Saint Louis University Pathogen Exposure Control Plan to use as a guide for training employees and for writing the protocol to be submitted to the Committee.

   See section XIV of this policy letter for details on how to obtain these documents.

2. Grant Applications: No grant or contract in which research using a pathogenic organism is proposed will be approved for submission to a funding agency until the Office of Environmental Safety has received notification of the intent of the principal investigator to submit a protocol for use of that organism in research. In some cases, depending on granting agency, full prior approval by the IBC is required prior to submission of the grant application. Consideration should be given to making early inquiry with the Biological Safety Officer to facilitate timely IBC review of the research protocol application.
3. **IBC Research Protocol Application Forms**: Forms for registering experiments using biohazards and recombinant organisms are available through the Office of Environmental Safety.

4. **Recombinant DNA Experiments Requiring IBC Review**: Types of recombinant DNA experiments that require approval by OBA and/or by the IBC prior to initiation include, but are not necessarily limited to, the following:

   a. Experiments involving the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
   b. Experiments involving the cloning of toxin molecules with an LD$_{50}$ of less than 100 nanograms per kilogram body weight.
   c. Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into one or more human research participants.
   d. Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into one or more human research participants.
   e. Experiments using Risk Group 2, Risk Group 3, Risk Group 4, Restricted Agents (as listed in the NIH Guidelines or the BMBL), or Select Agents as Host-Vector Systems.
   f. Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, Restricted Agents (as listed in the NIH Guidelines or the BMBL), or Select Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
   g. Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.
   h. Experiments involving whole animals.
   i. Experiments involving whole plants.
   j. Experiments involving more than 10 liters of culture.
   k. Experiments involving the formation of recombinant DNA molecules containing any portion of the genome of any eukaryotic virus.
   l. Experiments involving transgenic rodents.

5. **Exemptions from NIH Guidelines**: The following DNA molecules are exempt from the NIH Guidelines and registration with the Institutional Biosafety Committee.

   a. Those that are not in organisms or viruses
   b. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
   c. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely
related strain of the same species), or when transferred to another host by well established physiological means.
d. Those that consist entirely of DNA from an Eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
e. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.
f. Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment.

Refer to NIH Guidelines for further details on exemptions at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

6. **Impact of Violations**: Failure to gain approval of protocols before initiating research with a hazardous biological agent, or failure to register certain types of experiments utilizing recombinant organisms, can have far-reaching effects, including citation of the University and the investigator for possible violations of Federal Code and/or denial of federal funds for research to the investigator or the University. The Biosafety Committee may refer violations of this policy to the Research Integrity Officer for review under the Saint Louis University Research Integrity Policy.

7. **BSL-4 Organisms**: Organisms classified as requiring CDC Biosafety Level 4 (BSL-4) conditions can be carried out only within a few specialized laboratories in the United States and will not be conducted at Saint Louis University.

8. **BSL-3 Organisms**: Organisms requiring BSL-3 containment will be approved for use at Saint Louis University only in facilities that have the IBC’s approval as meeting BSL-3 standards. Refer to the BMBL for further details: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

9. **BSL-2 or BSL-1 Organisms**: Experiments requiring BSL-2 or BSL-1 containment will be expected to be carried out only in laboratories in which the requirements for the respective level of containment are carefully observed. Refer to the BMBL for further details: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

10. **IBC Review**: The committee will return the protocol to the principal investigator, either approved or with suggestions for revision of it to incorporate additional safeguards. If returned for revision, the principal investigator may request, in writing, a review of points with which he/she disagrees, and a meeting between the principal investigator and the IBC will be scheduled.
11. **Certification by all Lab Workers**: Following approval by the committee and the Director of Environmental Safety, the protocol must be read and signed by each person working in the affected laboratory, whether actually employed on the project described in the protocol or not. The signature of an employee or student on the approved protocol affirms that the signatory is aware of the hazard in the environment in which he or she works, and that he or she will abide by the precautions agreed to by the IBC in order to limit the probability of release of the hazard.

12. **Approvals**: Experiments involving recombinant DNA, gene therapy, select agents or other potentially hazardous agents covered by this policy and for which IBC is required before they may proceed will be reviewed by the IBC at a meeting at which a quorum is present. Following review, approvals will be granted as follows:
   a. **Full Approval**: Full approval will be granted by the IBC if there are no outstanding issues.
   b. **Contingent Approval**: Contingent approvals may be given by the IBC that only become effective upon the investigator satisfying any outstanding IBC safety requirements and recommendations identified by the IBC and communicated to the investigator. The removal of the contingency requires approval by executive action of the chairperson of the IBC.
   c. **External Approvals**: In the case of experiments requiring external review by an outside agency, any IBC approval granted shall be contingent upon approval being granted by the outside agency.
   d. **Approval of Experiments Requiring Registration Only**: In the case of recombinant DNA experiments requiring registration with the IBC, but not requiring approval of the IBC or an outside agency, the protocol will be approved by executive action of the chairperson of the IBC.
   e. **Investigator Agreement for All Approvals**: The principal investigator, upon receipt of approval, agrees to observe, at all times, the biological safety level containment required of that experiment.

13. **Amendment Applications**: Requests to amend a protocol or add another organism to the protocol must be submitted to the IBC and be approved prior to initiating a new line of investigation. Such submissions may be in memorandum form, clearly outlining changes from what was in the original protocol. When approved, the memorandum is to be affixed to the original document so that it is an integral part of that document.

14. **Renewal Applications**: Approved research protocol applications will be valid for a period of 5 years without requiring renewal, unless a significant amendment application results in a comprehensive resubmission of the research protocol application. In such cases, the 5-year renewal period will be dated from the approval date of the comprehensive amendment application.
15. **Annual Protocol Updates**: Once approved, the investigator is required to submit to the Office of Environmental Safety an annual update to the protocol, specifying changes in procedures, laboratory staff, or other relevant information. The Annual updates will be reviewed by the Biological Safety Officer and filed with the original approved application.

16. **Laboratory Inspections**: The IBC has an obligation to ascertain that experiments with infectious or recombinant organisms are safely managed. The Biological Safety Officer or other Office of Environmental Safety staff may conduct safety audits of facilities in which these types of experiments are performed at any time without prior notice.

17. **Training**: Anyone performing experiments with recombinant organisms, or those hazardous to man or the environment, must be well trained in proper microbiological technique to ensure minimization of risks. The assurance of proper training is the obligation and responsibility of the principal investigator or laboratory supervisor of the facility in which the hazard is used. OSHA requires that all training be documented in writing with date, names of participants and their signatures, and a list of topics covered. The Office of Environmental Safety can provide certain types of safety training upon sufficient advanced notice.

### X. SECURITY OF BIOLOGICAL AGENTS

1. **Physical Facility Security**: All biohazard agents, including recombinant DNA and all select agents, must be secured against unauthorized access or removal at all times. To this extent, the elements of physical facility security listed in the table below shall be in place for the particular agents as specified.

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<th>Biological Agent Physical Security Elements</th>
<th>Select Agents</th>
<th>Other Biohazards</th>
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<td><strong>Building Security</strong>: Building will be a “controlled access” building 24 hours per day, 7 days per week</td>
<td>Mandatory</td>
<td>Strongly Recommended</td>
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<td><strong>Laboratory Security</strong>: All laboratory entrances secured 24 hours per day, 7 days per week when laboratory staff are not physically present in the laboratory.</td>
<td>Mandatory</td>
<td>Mandatory</td>
</tr>
<tr>
<td><strong>Agent Security</strong>: All agents physically locked within their storage unit, e.g. refrigerator, freezer, cabinet, etc. when not in use.</td>
<td>Mandatory</td>
<td>Strongly Recommended</td>
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1 Routine housekeeping, maintenance and other services must be performed during daytime hours when laboratory staff is present in the laboratory.
2. **Data Security**: All data pertinent to select agents shall be securely stored. Methods of securing data include:

   a. **Isolated Computer**: An isolated computer that is not connected to any network may be used for storage of select agent data. Isolated computers shall not be used to access the Internet in any way, including via telephone modem. Isolated computers shall be stored in secured locations meeting the elements of “Building Security” and “Laboratory Security” delineated in the above table.

   b. **Networked Computer**: The use and storage of any data on a networked computer requires a highly secure network. The security of such network must be evaluated by Saint Louis University Information Technology Services network security experts prior to use of a networked computer for storage or communication of select agent data.

XI. **SELECT AGENT REGISTRATION & ACCESS**

1. **Select Agent Registration**: Select agents (see definitions in Section IV of this policy letter) are required to be registered with CDC prior to importation into Saint Louis University, as well as prior to exportation from Saint Louis University. The Biological Safety Officer, who is also the designated “Responsible Facility Official”, shall be contacted by any Saint Louis University investigator who anticipates the need to procure or transfer a select agent well in advance of the need to do so. Noncompliance with the Select Agent Rule can result in loss of NIH funding, as well as civil penalties. IMPORTANT! See the following WEB link for important details that may be applicable to your research: http://www.cdc.gov/od/ohs/lrsat.htm

2. **Select Agent Access**: The regulation of select agents is mandated by various legislative acts focused on preventing the use of these agents in terrorism. In October 2001, the USA PATRIOT Act was signed into law by the President of the United States. Consistent with the intent of the USA PATRIOT Act, this Saint Louis University Policy Letter requires that the following procedures be adhered to:

   a. No restricted person, as defined in Section IV of this policy, shall have access to any select agent in Saint Louis University laboratories.

   b. No restricted person shall have access to laboratories where select agents are used in experiments.

   c. It is the responsibility of the principal investigator to enforce this policy within their research laboratories.

   d. It is the responsibility of each department chairperson to implement and enforce this policy within his or her department.
XII. PACKAGING, SHIPMENT, EXPORT, RECEIPT & IMPORTATION OF BIOLOGICAL AGENTS

1. **Packaging & Shipment:** No person shall handle, offer for transport, or transport biological agents unless they are trained in accordance with Department of Transportation (DOT) and International Air Transport Association Dangerous Goods Regulations. Function specific training is required for packaging, labeling, manifesting, and/or transport of biological agents, including clinical specimens. To arrange for the necessary training, contact the Office of Environmental Safety’s Biological Safety Officer at least two weeks in advance of anticipated need to ship a biological agent.

2. **Export of Infectious Materials:** The Biological Safety Officer shall be contacted at least four weeks in advance of anticipated need to ship a biological agent internationally or to distribute an imported biological agent domestically, in order to comply with the following requirements.
   
   a. **International Exports:** The export of a biological agent internationally may require a license from the Department of Commerce and registration with the CDC.
   
   b. **Distribution of Imported Biological Agents With The United States:** The distribution of an imported biological agent within the United States may require a permit issued by the CDC Director and registration with the CDC.

3. **Receipt:** Prior to initiating an action resulting in receipt of a biological agent from any external or internal supplier (i.e., includes other Saint Louis University faculty, staff or students) approval of the IBC is required, as delineated below:
   
   a. If IBC approval is required prior to working with the biological agent, and such approval has not been obtained.
   
   b. If IBC approval has already been granted to work with the biological agent, further approval of the IBC is not required; however if the agent is being obtained from a foreign supplier, the requirements delineated in paragraph 4 below shall be met specific to the agent and supplier in question.

   It is the principal investigator’s responsibility to notify the Biological Safety Officer of the need to obtain approval for a biological agent well in advance of the anticipated need to receive the agent.

4. **Importation:** Prior to initiating importation of a biological agent from any foreign country, the principal investigator must notify the Biological Safety Officer well in advance of the need to receive the agent. In order to legally import many biological agents, compliance with the following may be required:
a. An import permit issued by the Director of the CDC must be obtained by the importer.

b. The importer is legally responsible for assuring that the foreign personnel package, label, and ship the infectious materials in accordance with the following federal regulations:
   - U.S. Public Health Service regulations (42 CFR Part 72 – Interstate Shipment of Etiologic Agents)
   - International Air Transport Association (IATA) Dangerous Goods Regulations.

c. A United States Department of Agriculture (USDA) permit may be required.

XIII. CONFLICT OF INTEREST

No member of the Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

XIV. MEMBERSHIP TERMS

Appointments to the Institutional Biosafety Committee shall generally be for three-year renewable terms.

XIV. REFERENCES


2. Saint Louis University Pathogen Exposure Control Plan. A copy of this document should be in any laboratory in which work with pathogenic organisms is performed. Request a copy from the Saint Louis University Office of Environmental Safety.

3. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, 1999. A copy of this document, jointly produced by the Centers for Disease Control and the National Institutes of Health, should be available to investigator’s contemplating work with pathogenic organisms. A copy of this document, commonly referred to
as the BMBL, can be downloaded via the WEB at: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

4. [42 CFR 72.6:](http://www.cdc.gov/od/ohs/lrsat.htm) Additional Requirements for Facilities Transferring or Receiving Select Agents (CDC)

XVI. **RECISSION**

Health Sciences Policy Letter No. 3, Appendix 3.17 (Biological Safety Committee) dated December 1, 1996.

XVII. **REVIEW DATE**

This policy letter will be reviewed every 3 years or an as-needed basis. In all cases, Federal and state requirements take precedence over particular provisions of this policy.

APPROVED:

Sandra H. Johnson, J.D., LL.M.
Provost

Date: 4-1-02